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This report

Abstract

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Background: Obesity is twice as common in people with schizophrenia as in the general population. The National Institute for Health and Care Excellence guidance recommends that people with psychosis or schizophrenia, especially those taking antipsychotics, be offered a healthy eating and physical activity programme by their mental health care provider. There is insufficient evidence to inform how these lifestyle services should be commissioned.

Objectives: To develop a lifestyle intervention for people with first episode psychosis or schizophrenia and to evaluate its clinical effectiveness, cost-effectiveness, delivery and acceptability.

Design: A two-arm, analyst-blind, parallel-group, randomised controlled trial, with a 1 : 1 allocation ratio, using web-based randomisation; a mixed-methods process evaluation, including qualitative case study methods and logic modelling; and a cost–utility analysis.

Setting: Ten community mental health trusts in England.

Participants: People with first episode psychosis, schizophrenia or schizoaffective disorder.

Interventions: Intervention group: (1) four 2.5-hour group-based structured lifestyle self-management education sessions, 1 week apart; (2) multimodal fortnightly support contacts; (3) three 2.5-hour group booster sessions at 3-monthly intervals, post core sessions. Control group: usual care assessed through a longitudinal survey. All participants received standard written lifestyle information.

Main outcome measures: The primary outcome was change in weight (kg) at 12 months post randomisation. The key secondary outcomes measured at 3 and 12 months included self-reported nutrition (measured with the Dietary Instrument for Nutrition Education questionnaire), objectively measured physical activity measured by accelerometry [GENEActiv (Activinsights, Kimbolton, UK)], biomedical measures, adverse events, patient-reported outcome measures and a health economic assessment.

Results: The trial recruited 414 participants (intervention arm: 208 participants; usual care: 206 participants) between 10 March 2015 and 31 March 2016. A total of 341 participants (81.6%) completed the trial. A total of 412 participants were analysed. After 12 months, weight change did not differ between the groups (mean difference 0.0 kg, 95% confidence interval –1.59 to 1.67 kg; $p = 0.964$); physical activity, dietary intake and biochemical measures were unchanged. Glycated haemoglobin, fasting glucose and lipid profile were unchanged by the intervention. Quality of life, psychiatric symptoms and illness perception did not change during the trial. There were three deaths, but none was related to the intervention. Most adverse events were expected and related to the psychiatric illness. The process evaluation showed that the intervention was acceptable, with participants valuing the opportunity to interact with others facing similar challenges. Session feedback indicated that 87.2% of participants agreed that the sessions had met their needs. Some indicated the desire for more ongoing support. Professionals felt that the intervention was under-resourced and questioned the long-term sustainability within current NHS settings. Professionals would have preferred greater access to participants' behaviour data to tailor the intervention better. The incremental cost-effectiveness ratio from the health-care perspective is £246,921 per quality-adjusted life-year (QALY) gained and the incremental cost-effectiveness ratio from the societal perspective is £367,543 per QALY gained.

Conclusions: Despite the challenges of undertaking clinical research in this population, the trial successfully recruited and retained participants, indicating a high level of interest in weight management interventions; however, the STEPWISE intervention was neither clinically effective nor cost-effective. Further research will be required to define how overweight and obesity in people with schizophrenia should be managed. The trial results suggest that lifestyle programmes for people with schizophrenia may need greater resourcing than for

other populations, and interventions that have been shown to be effective in other populations, such as people with diabetes mellitus, are not necessarily effective in people with schizophrenia.

Trial registration: Current Controlled Trials ISRCTN19447796.

Contents

List of tables

List of figures

List of boxes

Glossary

Blinded/blinding Concealment of group allocation from individuals involved in a randomised controlled trial.

F20 The *International Classification of Diseases*, Tenth Revision, code for schizophrenia.

F25 The *International Classification of Diseases*, Tenth Revision, code for schizoaffective disorder.

First episode psychosis First episode psychosis is defined as 3 years since presentation to mental health services.

Framework analysis A qualitative method, suited for applied policy research.

Logic model A tool used to evaluate the implementation of a programme of care.

NVivo (QSR International, Warrington, UK) A computer software package for qualitative data analysis.

Stata® (StataCorp LP, College Station, TX, USA) A computer software package for statistical analysis.

Triangulation A method used by qualitative researchers to establish trustworthiness by comparing the findings of different methods or perspectives.

List of abbreviations

B-IPQ	Brief Illness Perception Questionnaire	LDC	Leicester Diabetes Centre
BMI	body mass index	MAR	missing at random
BPRS	Brief Psychiatric Rating Scale	MNAR	missing not at random
CACE	complier-average causal effect	MVPA	moderate or vigorous physical activity
CEAC	cost-effectiveness acceptability curve	NICE	National Institute for Health and Care Excellence
CI	confidence interval	NIHBCC	National Institutes for Health Behaviour Change Consortium
CMHT	Community Mental Health Team		
CONSORT	Consolidated Standards of Reporting Trials	NIHR	National Institute for Health Research
CQUIN	Commissioning for Quality and Innovation	NPT	normalisation process theory
		OPCRIT+	Operational Criteria Checklist for Psychotic Illness and Affective Illness
CRF	case report form		
CSRI	Client Service Receipt Inventory	PHQ-9	Patient Health Questionnaire-9
CTRU	Clinical Trials Research Unit	PI	principal investigator
DESMOND	Diabetes Education and Self-Management for Ongoing and Newly Diagnosed	PSSRU	Personal Social Services Research Unit
		QALY	quality-adjusted life-year
DINE	Dietary Instrument for Nutrition Education	QoL	quality of life
		RCT	randomised controlled trial
DOT	DESMOND Observation Tool	SD	standard deviation
ENMO	Euclidean norm minus one	SF-36	Short Form questionnaire-36 items
EQ-5D	EuroQol-5 Dimensions	SF-6D	Short Form questionnaire-6 Dimensions
EQ-5D-5L	EuroQol-5 Dimensions, five-level version		
		SMD	standardised mean difference
GEE	generalised estimating equation	STEPWISE	STructured lifestyle Education for People WIth SchizophrEnia, schizoaffective disorder and first episode psychosis programme
GP	general practitioner		
HbA$_{1c}$	glycated haemoglobin		
ICD-10	*International Classification of Diseases,* Tenth Revision		
		TAU	treatment as usual
ICER	incremental cost-effectiveness ratio	TDF	theoretical domains framework
ICF	International Classification of Functioning		

Plain English summary

People with schizophrenia are often overweight. Losing weight and being more active can reduce the risk of diabetes mellitus and heart disease and dying early. The NHS recommends offering a weight loss programme; however, mental health care providers do not know how best to do this.

We assessed whether or not an education programme to help people with psychosis to lose weight would be better than the usual care provided by the NHS.

A total of 414 people took part. We selected half of them at random to attend an education programme run by trained facilitators. The other half received their usual health care.

We found no important difference in weight between the two groups, at either 3 months or 12 months. We also found that the programme did not provide good value for money. In interviews, service users said that they liked the education programme and that it helped them to eat healthily and lose weight. However, we found no change in their diet and activity levels in either group. The trained staff thought that the programme could benefit service users, but were unsure if the NHS could afford it. They also wanted to know whether or not service users were losing weight during the programme.

People were interested in the trial and stayed in the trial until the end. Unfortunately, although some people benefited, the programme did not work for most people. Therefore, we need to look for better ways to help people with psychosis to lose weight.

Scientific summary

Background

Schizophrenia is a psychotic illness that affects around 1% of the population. The prevalence of obesity in people with schizophrenia is approximately twofold higher than that in the general population and is associated with higher levels of morbidity, especially cardiovascular disease, diabetes mellitus and early mortality.

Objectives

- To develop a group-based, structured self-management lifestyle education programme for people with schizophrenia, schizoaffective disorder and first episode psychosis.
- To conduct a multicentre randomised controlled trial (RCT) to investigate whether or not the intervention leads to a clinically important difference in weight change, as well as physical activity and diet, compared with usual care.
- To conduct a mixed-methods process evaluation to explore intervention delivery and participant and facilitator experiences, and to explain discrepancies between expected and observed outcomes.
- To conduct an economic evaluation of the intervention.
- To assess the fidelity of intervention delivery when undertaken at 10 different sites.

Design

Intervention development
The intervention development was guided by the Medical Research Council framework for complex interventions: (1) identifying the evidence base through a literature review; (2) identifying/developing a theory and modelling the process and outcomes, through consultation with service users and health professionals; and (3) four plan–do–study–act cycles incorporating qualitative interviews.

Randomised controlled trial
The trial was a two-arm, parallel-group RCT with a 1 : 1 allocation ratio, using web-based randomisation and with the principal investigator and analysts being blinded to allocation until after the final analysis.

Mixed-methods process evaluation
The process evaluation used three main approaches:

1. logic modelling, integrating contextual factors with the National Institute for Health Behaviour Change Consortium fidelity framework and Linnan and Steckler's process evaluation framework
2. a qualitative single-case design, with the unit of analysis variably at the participant level ($n = 24$ participants) and at the level of the experimental intervention programme ($n = 20$ facilitator interviews)
3. a triangulation protocol to compare quantitative process data with qualitative findings.

Economic evaluation
The economic evaluation was undertaken from a health and social care and societal perspective and included the costs of medicines and NHS professionals in primary and community care and inpatient settings, as well as social care costs (including costs of education, and employment and informal care). The cost-effectiveness of the physical activity and healthy eating programme was assessed by combining costs with the primary outcome and quality-adjusted life-years (QALYs) generated from the EuroQol-5 Dimensions, five-level version (EQ-5D-5L) questionnaire.

Fidelity of the intervention delivery

Fidelity was assessed by facilitator talk time and direct observation of the facilitator behaviour and conduct at sessions.

Setting

Community settings in 10 UK mental health NHS trusts.

Participant selection and recruitment

Potential participants were eligible for inclusion if they were adults aged $\geq$ 18 years with a diagnosis of schizophrenia, schizoaffective disorder or first episode psychosis, were being treated with an antipsychotic drug, were willing and able to give consent and to attend group education sessions delivered in English, and had a body mass index of $\geq$ 25 kg/m^2 ($\geq$ 23 kg/m^2 for adults with South Asian and Chinese backgrounds) or were concerned about weight. People with physical illnesses that could seriously reduce life expectancy or affect metabolic measures or weight gain were excluded. Those with a primary diagnosis of a learning disability, who were currently pregnant or < 6 months post partum, who had significant alcohol or substance misuse or a (tentative) diagnosis of psychotic depression or mania or were currently (or within the past 3 months) engaged in a systematic weight management programme were also excluded.

Intervention development study

Twenty-four service users were recruited between May and December 2014 in four waves at one centre (Sheffield) to refine a prototype intervention before the RCT.

Randomised controlled trial

Between 10 March 2015 and 31 March 2016, 1223 adults with schizophrenia, schizoaffective disorder or first episode psychosis were screened for eligibility. A total of 423 consented to participate in the trial and 414 participants (target: $n = 396$) were randomised (intervention arm, $n = 208$ participants; usual care, $n = 206$ participants).

Interventions

All participants received standardised written lifestyle information about diet, physical activity, smoking and alcohol use. The use of external weight loss programmes was permitted at the individual level.

The intervention group received a complex intervention based on Bandura's self-efficacy theory, Leventhal's self-regulation theory and Marlatt and Gordon's relapse prevention model. The programme comprised (1) four 2.5-hour group-based structured lifestyle self-management education sessions, 1 week apart, facilitated by trained professionals delivering manualised content; (2) fortnightly support contacts from facilitators (face to face or via telephone, mail or e-mail, by participant preference); and (3) three 2.5-hour group booster sessions delivered at 3-monthly intervals post core sessions, reinforcing further behaviour change/self-management strategies.

The control group received treatment as usual, captured through a survey at the site level and a health and social care resource questionnaire.

Main outcome measures

The main outcome measures were weight change (primary outcome at 12 months), body mass index, waist circumference, objectively measured physical activity [wrist-worn GENEActiv (Activinsights, Kimbolton, UK) accelerometer], adapted Dietary Instrument for Nutrition Education questionnaire, blood pressure, fasting glucose, lipid profile, glycated haemoglobin, health state utility (EQ-5D-5L), Short Form questionnaire-36 items, Brief Illness Perception Questionnaire [(B-IPQ) weight], Brief Psychiatric Rating Scale, health and social care resource use (Client Service Receipt Inventory), Patient Health Questionnaire 9-item depression scale, weight loss programmes, session feedback (intervention only) and adverse events. Analyses were undertaken on an intention-to-treat basis, with the treatment effect adjusted for the baseline value, recruiting site, years since the person started antipsychotic treatment and the clustering effect of the course attended.

Results

The trial closed on 31 March 2017, with 341 (81.6%) participants completing the trial. Forty-seven (25 intervention, 22 control) participants withdrew consent, three died (intervention) and 21 (11 intervention and 10 control) participants were lost to follow-up. The intention-to-treat analysis excluded two participants (control); one was erroneously randomised, having previously not consented, and one withdrew all consent to use their data. Therefore, 412 (207 intervention and 205 control) participants were included in the analyses. Two hundred and ten participants (51.0%) were male, 349 participants (84.7%) were white European and the average age was 40 years.

Randomised controlled trial outcomes

At baseline, the groups were well balanced; however, the intervention group participants were, on average, 3 kg heavier at baseline, which is partially explained by the higher proportion of men in the intervention arm (55.6% vs. 46.3%). Three hundred and forty-nine participants (84.7%) had a diagnosis of schizophrenia or schizoaffective disorder and 63 (15.3%) were categorised as having first episode psychosis. One hundred and eleven intervention group participants (53.6%) attended three or more core sessions and one or more booster sessions; 36 participants (17.4%) did not attend any intervention sessions.

After 12 months, the primary outcome of weight change (kg) was almost identical between the trial arms, with a non-significant mean reduction in weight of 0.47 kg in the intervention group and 0.51 kg in the control group (difference = 0.0 kg, 95% confidence interval –1.59 to 1.67 kg; $p = 0.964$). Weight change by centre varied, with 15 intervention participants at one centre losing an average of 4 kg [standard deviation (SD) 4.30 kg] and 18 control group participants gaining on average 3 kg (SD 4.30 kg). In contrast, 21 intervention participants at another centre lost an average of 0.5 kg (SD 6.89 kg), whereas 24 participants in the control group lost 3 kg (SD 9.15 kg). There were no significant differences in change in weight, body mass index or waist circumference at the 3- and 12-month assessments. Laboratory and vital signs were unchanged at 12 months.

The intervention had no overall effect on dietary intake, as measured by the Dietary Instrument for Nutrition Education (DINE); physical activity at baseline was similarly low in both groups. At the 3-month assessment, weekend moderate or vigorous physical activity was significantly higher in the intervention arm, but this difference had disappeared by 12 months.

Self-reported quality of life (QoL), measured using the Short Form questionnaire-36 items, suggested higher QoL post randomisation in the intervention group for physical functioning and bodily pain, but a higher level of emotional well-being in the control group. On the main measure of the EQ-5D-5L, there was no significant difference between the groups. However, on the 'thermometer' health scale, the control group showed more improvement at 12 months, with a difference of 4.4 points ($p = 0.028$). For self-reported depressive symptoms, measured using the Patient Health Questionnaire-9, there was minimal change in both groups over time. In terms of perceptions of weight problems, the B-IPQ total score showed a small improvement in both groups over time, although the changes in the eight dimensions of the B-IPQ were mixed. There were

no significant differences between the groups for the total score or any dimension. For both groups, the observer-rated Brief Psychiatric Rating Scale showed little change over time, with no significant difference between groups.

Twelve participants (eight in the control arm and four in the intervention arm) attended one or more weight loss programmes outside the trial at 3 months, of whom five were still attending at 12 months. At 12 months, 25 participants (7.4%; 8 in the control arm and 17 in the intervention arm) reported attending a weight loss programme outside the trial.

Anonymous intervention session feedback was invited at all seven group sessions, and 708 forms were returned. Overall, the majority (≈90%) of responses were positive, with 87.2% of participants agreeing that the sessions had met their needs. Three-quarters of the free-text comments were also positive. As feedback could not be linked to individual outcomes, these were analysed by centre (five were excluded, owing to no site code). There were no significant correlations between mean weight change and mean feedback scores for centres at 3 or 12 months (Spearman's rank-order correlation = –0.20, $p = 0.476$, and Spearman's rank-order correlation = 0.042, $p = 0.454$, respectively).

Adverse events

A total of 46 adverse events occurred in 37 intervention participants and 34 adverse events occurred in 26 control participants. Fifty per cent of adverse events in both groups were psychiatric hospitalisation. Four deaths were reported, all in the intervention group; the causes were pulmonary embolism following a ruptured Achilles tendon; left ventricular hypertrophy, hypertension and obesity; diabetic ketoacidosis leading to cardiac arrest; and myocardial infarction. Three of the deaths occurred during the trial and one occurred 37 days after trial completion.

Cost-effectiveness

The incremental cost-effectiveness ratio (ICER) from the health-care perspective was £246,921 per QALY gained and the ICER from the societal perspective (including employment and education for patients and informal care) was £367,543 per QALY gained.

Process evaluation

Both the participants and the facilitators described how the intervention was popular and well received. The participants particularly enjoyed meeting others facing the same challenge of managing weight. It was relatively easy to fill places on the STructured lifestyle Education for People WIth SchizophrEnia, schizoaffective disorder and first episode psychosis programme (STEPWISE) course, indicating a high level of interest in weight management programmes among people with severe mental illness.

The process evaluation found potential barriers to self-management at the level of the individual's psychological functioning (e.g. cognitive or attention deficit) and participative capabilities (e.g. low income, anxiety about social interaction), as well as the attitudes of family members and health professionals (paternalism and gatekeeping). Detailed case studies suggested that achieving and maintaining weight loss was particularly difficult for those with first episode psychosis (< 3 years since antipsychotic treatment initiation) and for those with more severe symptoms.

Interviews with developers suggested that the intervention was well grounded in behaviour change theory and had a high level of acceptability to participants. Facilitators reported that they understood and constructed value for the intervention, but were sometimes sceptical about the commitment of senior NHS management to the programme and rarely felt adequately resourced at an organisational level. They would have preferred to have been kept abreast of changes in body weight to assess the effects of the programme on its participants. Facilitators anticipated changing STEPWISE if adopted at the sites, or integrating ideas from it into their own practice if it did not. Although there were opportunities for sharing stories and action-planning, facilitators felt that they needed greater feedback on biomedical and lifestyle data during the sessions to support individuals better.

Analysis against the logic model highlighted the potential role for quality assurance infrastructure in raising and maintaining the quality of delivery. Facilitator training courses and materials were valued and facilitators were generally skilled and motivated. Senior management commitment was generally good, but this did not always translate into appropriate resourcing, and gatekeepers did not always refer eligible patients. The availability of taxi fares for group attendance played a key part in patient engagement. The work of programme and case management was almost always described as inadequately resourced and the number of facilitators who left the trial was high (an average of 20% over 40 weeks). The reason for this was not formally assessed but was often related to work promotions rather than discontent with the intervention.

The fidelity assessment indicated that the delivery was largely as planned, with the mental health care professionals avoiding didactic teaching while adopting facilitative behaviours that allowed the participants to contribute to the groups.

Conclusions

Despite concerns about the ability to recruit and retain people with schizophrenia, the STEPWISE trial was completed successfully within the original time frame; however, the STEPWISE intervention was neither clinically effective nor cost-effective. Current National Institute for Health and Care Excellence guidance recommends that lifestyle programmes should be offered to people with severe mental illness, but does not state how these should be commissioned. The results of this trial suggest that lifestyle programmes that have been shown to be effective in other populations, such as in people with diabetes mellitus, are not necessarily effective in people with schizophrenia.

Recommendations for research

Further research should investigate if:

- a more intensive lifestyle management programme with longer periods of maintenance support, complemented by objective measures of weight, diet and exercise, delivered by more experienced facilitators or by people from different professional backgrounds is clinically effective and cost-effective
- a more flexible approach, including both group and one-to-one sessions, is more effective
- a broader approach, incorporating adjustment of antipsychotic treatments and the use of adjunctive pharmacological interventions, may be required
- it is possible to overcome the barriers to attendance at lifestyle management programmes
- other formats, including family members or carers, would be more effective
- lifestyle management programmes should be tailored on the basis of the duration of psychotic illness; for example, preventative approaches for people with first episode psychosis may need to be different from those for people with more established disease
- a lifestyle intervention should be combined with specific medication review and/or pharmacological approaches to weight management.

Trial registration

This trial is registered as ISRCTN19447796.

Funding

Chapter 1 Introduction

Obesity and weight gain in people with schizophrenia

Schizophrenia, a psychotic illness, affects ≈1% of the population. Mortality rates in people with schizophrenia are increased twofold to fourfold, with life expectancy reduced by 10–20 years.[1–3] Around 75% of people with schizophrenia die from physical illness, most commonly cardiovascular disease. Weight gain is a key contributor to excess morbidity and mortality, with obesity being two or three times more prevalent in people with schizophrenia than in the general population.[4] The rates of obesity have increased substantially and have risen faster than in the general population over the past three decades.[5]

The cause of the increase in obesity is multifactorial and includes environmental factors (such as poverty, urbanisation, poor diet[6,7] and physical inactivity), disease effects (such as altered neuroendocrine functioning, altered reward perception) and treatment effects; antipsychotics cause weight gain in 15–72% of patients.[8] Weight gain is observed early in treatment; between 37% and 86% of people with a first episode of psychosis gain > 7% of their body weight over 12 months.[9] Much of this weight gain occurs within 12 weeks of treatment initiation[10] but continues in the longer term, albeit at a slower rate.[11]

Interventions to control or reduce antipsychotic-related weight gain

The British Association of Psychopharmacology has reviewed interventions designed to promote weight loss or attenuate weight gain in people taking antipsychotics. Given the underlying mechanisms associated with weight gain, these have taken three, usually exclusive, approaches: (1) lifestyle interventions to improve diet and physical activity, (2) adjustment of antipsychotic medication to minimise the use of drugs associated with the greatest weight change and (3) the use of adjunctive medications that may attenuate the antipsychotic effect. The STructured lifestyle Education for People WIth SchizophrEnia, schizoaffective disorder and first episode psychosis programme (STEPWISE) intervention was intended to promote weight loss through lifestyle modification. However, when the intervention was designed, the developers also considered the effect of the illness and treatment and how these could interact with lifestyle modification.

Prior to the STEPWISE project, a systematic review of randomised controlled trials (RCTs) reported that non-pharmacological interventions lead to a mean 3.12-kg weight reduction over a period of 8–24 weeks in people with schizophrenia, with commensurate change in other cardiovascular risk factors.[12] Programmes offered benefits regardless of treatment duration, modality (individual vs. group setting), behaviour change versus educational content or whether they aimed to prevent weight gain or promote weight loss. Most interventions contained cognitive behavioural elements as well as diet or exercise-based content. The sample size of RCTs was generally small (median 53, range 15–110) and most participants were not followed up beyond 12 weeks. Of the few studies with long-term follow-up, not all sustained long-term weight control.[13] The systematic review team called for larger trials with long-term follow-up and a focus on weight maintenance following initial intervention.

The 2014 National Institute for Health and Care Excellence (NICE) guidance on psychosis and schizophrenia in adults[14] expanded this review to 24 studies with similar conclusions. Several of these studies included significant numbers of individuals with other types of mental illness, for whom the strategies needed to promote weight loss may be different. Consistent with the earlier systematic review, few studies examined weight change beyond 6 months, and only six studies included > 100 participants. No study was undertaken in the UK, most were rated as being at moderate risk of bias and there was substantial heterogeneity of effect size. NICE concluded that lifestyle interventions were effective in reducing and maintaining body weight in the short term, but, without longer-term data, the effects beyond 6 months were unknown.

The most recent systematic review published in August 2017 included 17 studies and 1968 participants.[15] Sixty-six per cent of participants had schizophrenia spectrum disorders. Consistent with previous publications, the 10 studies reporting short-term interventions of < 6 months' duration showed greater weight loss than usual care [standardised mean difference (SMD) –0.20, 95% confidence interval (CI) –0.34 to –0.05], but with significant heterogeneity in response. The six studies that reported interventions lasting longer than 1 year showed a more consistent weight reduction (SMD –0.24, 95% CI –0.36 to –0.12). However, within this group, only two of the six studies achieved a statistically significant weight loss, both of which included people with other severe mental illnesses.

Although some weight loss programmes have promoted behaviour change through intensive one-to-one counselling strategies, resource scarcity in many health services makes the sustainability of such programmes challenging.[16] An alternative is structured education, which encompasses patient-centred, group educational programmes with a clear philosophy, a written curriculum and a basis in behaviour change theory and empirical data and is delivered by trained, quality-assessed educators.[17] The NICE diabetes mellitus prevention guidance advocates structured education as a potentially cost-effective method for the promotion of self-management and behaviour change in people with chronic disease.[18]

The Leicester Diabetes Centre structured education approach

The STEPWISE intervention was developed by the Leicester Diabetes Centre (LDC), using the same process used in developing the Diabetes Education and Self-Management for Ongoing and Newly Diagnosed (DESMOND) programme.[19] The DESMOND programme and other adaptations have effectively promoted lifestyle change and induced weight loss in multicentre RCTs. The curricula promote physical activity, a healthy diet and weight loss by encouraging self-regulation through self-monitoring (feedback), relapse prevention (identifying and addressing barriers to change) and goal-setting strategies. It incorporates standardised educator training and a quality assurance programme.

Rationale and objectives

Rationale

Pragmatic interventions that offer long-term weight control or reduction in people with schizophrenia or first episode psychosis are needed. The STEPWISE trial aimed to evaluate if a structured lifestyle education programme, delivered in a community mental health setting, supported weight loss at 1 year in adults with schizophrenia, schizoaffective disorder or first episode psychosis.

Objectives

- To develop a group-based, structured self-management lifestyle education programme for people with schizophrenia, schizoaffective disorder and first episode psychosis.
- To conduct a multicentre RCT to investigate if the intervention leads to a clinically important difference in weight change, as well as physical activity and diet, compared with usual care.
- To conduct a mixed-methods process evaluation to explore intervention delivery, participant and facilitator experiences and explain discrepancies between expected and observed outcomes.
- To conduct an economic evaluation of the intervention.
- To assess the fidelity of intervention delivery when undertaken at 10 different sites.

Chapter 2 Intervention development

The aim of the intervention development phase was to develop a sustainable evidence-based programme to support people with schizophrenia, schizoaffective disorder or first episode psychosis with their weight management in a way that is acceptable and feasible to deliver within NHS settings and available resources. The intervention was developed by a team from the LDC, together with expert colleagues, patients and public involvement.

Literature review

The meta-analysis of non-pharmacological interventions designed to address antipsychotic-associated weight gain by Caemmerer and colleagues[12] was updated by re-running the search strategy across the PsycINFO, MEDLINE, PubMed, Cumulative Index to Nursing and Allied Health Literature (CINAHL) and Cochrane Library databases using the original search terms, and only one further paper was identified.[20]

The literature review reported the benefits of non-pharmacological interventions, but the effectiveness did not differ between modalities or intervention duration, or between interventions that employed group-based versus individual approaches. The only difference was the benefit of outpatient over inpatient interventions. Some studies suggested that nutritional interventions were more effective than cognitive–behavioural therapy, but there was considerable overlap between interventions, making these distinctions difficult to determine. Most interventions ran as 12–24 weekly sessions, delivered either in groups or individually. Some interventions provided specific cardiovascular exercise training. Common dietary themes included:

- reading food labels
- switching drinks from full sugar to low calorie
- eating healthy snacks
- eating more slowly and deliberately
- recognising satiety.

Several used 'psychoeducation', but further details were not specified, and a theoretical basis was reported in only one study that employed social cognition theory.[21]

Development of a theoretical framework

As the theoretical basis of the interventions was specified in only one paper, despite this being widely considered to be good practice,[22] we used the wider behaviour change and weight management literature to inform our approach. We considered three key areas that are core to weight management interventions in people with schizophrenia:

1. behaviour change theory, specifically with a focus on food and physical activity
2. the psychological processes underlying weight management
3. the challenges of living with psychosis and the impact on eating and weight.

These core factors determined the draft theoretical framework that guided the overall intervention development (*Figure 1*). We thus ensured a focus on key hypothesised problem behaviours, were clear about the receipt of the intervention by participants[24] and thus applied appropriate behaviour change techniques.[25,26] The intervention was inspired by a number of theories, but systematically employed three (*Table 1*), and intervention components were coded using the behaviour change taxonomy.[25]
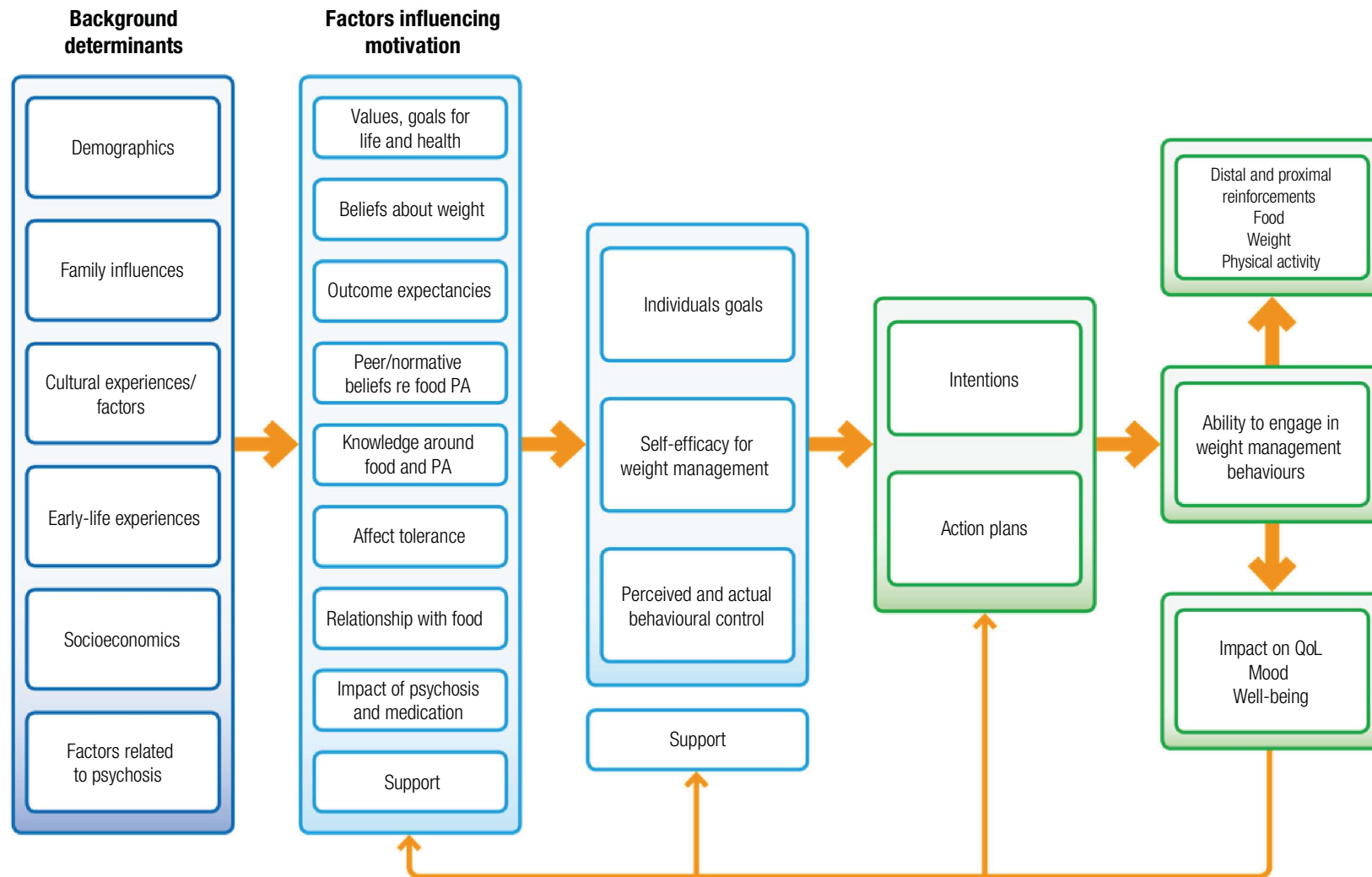
FIGURE 1 Theoretical framework of the STEPWISE intervention. Reproduced from Holt *et al.*[23] This is an Open Access article distributed in accordance with the terms of the Creative Commons Attribution (CC BY 4.0) license, which permits others to distribute, remix, adapt and build upon this work, for commercial use, provided the original work is properly cited. See: http://creativecommons.org/licenses/by/4.0/. The figure includes minor additions and formatting changes to the original text.

TABLE 1 Development of the Intervention based on the three core theories

Identified target behaviour/problem	Theory	Participant receipt and potential behavioural outcome	Intervention on the STEPWISE course	Mapping to behavioural taxonomy
Belief about weight problems (e.g. because of their medication, they can have no impact on their weight)	Self-regulation theory – specifically, illness representations around weight management • Signs of a weight problem • Causes • Consequences • Treatment • How long it will last	To have identified their own potential erroneous beliefs and questioned these in order to directly influence their decisions around weight management	'Your story' session: elicit participants' beliefs about what caused their weight problem, what 'treatment' would help to manage it, the consequences for them and their health Topic sessions: information sessions throughout the course, specifically the impact of medication on their weight and the strategies that they can employ to manage their weight	Not completely specified, but included in: • information about health consequences • framing/reframing
Low levels of confidence around being able to engage in successful weight management, possibly related to multiple unsuccessful attempts at sustained weight loss	Self-efficacy • Mastery (previous successful attempts at the behaviour) • Modelling (observing others engaging in the behaviour) • Verbal persuasion (talking through the process of change, expecting success) • Emotional arousal (managing the emotional barriers to change, particularly anxiety around change and fear of failure)	Increased belief in their ability to engage successfully in weight management. Identified strategies to increase their self-efficacy and engage in behaviour change	'Sharing stories' session: eliciting what has gone well in terms of behaviour change, problem-solving around challenges and observing and learning from others' successes and problem-solving. Discussing feelings as activators of, and barriers to, change Next steps: action-planning, identifying barriers, problem-solving and setting small graded tasks	• Focus on past successes • Self-monitoring outcomes of behaviour and consequences • Instruction on how to perform the behaviour • Graded tasks • Behavioural experiments • Credible source • Habit reversal • Review behavioural goals • Social comparison • Focus • Goal-setting • Action-planning • Problem-solving • Information about antecedents • Information about emotional consequences • Reduce negative emotions • Self-incentive • Self-reward

continued

TABLE 1 Development of the Intervention based on the three core theories (*continued*)

Identified target behaviour/problem	Theory	Participant receipt and potential behavioural outcome	Intervention on the STEPWISE course	Mapping to behavioural taxonomy
Maintenance of behaviour change, particularly as there are strong cues to previous behaviours and thus high likelihood of relapse	Relapse prevention model: • High-risk situations with strong cues need to be managed by avoidance or coping strategies • Coping strategies need to be prepared in advance • Management of relapse will result in increased self-efficacy	Reviewed the situations that would most likely result in relapse. Developed plans of how to manage these when they occur View relapse as a natural part of the change process and as an opportunity to learn rather than berate themselves and reinforce a potential negative self-perception	Keeping it going: visual tools and interactive exercises to explore potential sources of relapse and develop plans to overcome this when it occurs	• Self-monitoring of behaviour • Information about antecedents • Behaviour assessment • Goal-setting • Problem-solving • Action-planning • Review behavioural goals • Restructuring physical and social environment • Avoidance/reducing exposure to cues for behaviour • Reduce negative emotions • Prompts • Remove access to the reward • Framing/reframing • Verbal persuasion about capacity

Note

Intervention development

Initially, we planned to adapt the STEPWISE programme from the DESMOND 'Let's Prevent Type 2 Diabetes programme' intervention, which seeks to promote lifestyle changes in people who are at an increased risk of developing type 2 diabetes mellitus, and results in modest benefits in biomedical and lifestyle outcomes. Although significant weight change was not achieved, progression to diabetes mellitus in those who were at risk of developing it decreased.[27] However, it rapidly became apparent from the literature review, early meetings with stakeholders and the expert opinions of health-care professionals actively providing local weight management interventions in mental health settings that, although the underlying principles of the Let's Prevent Type 2 Diabetes programme were relevant, the programme itself was not suitable for people with schizophrenia.

The STEPWISE intervention was therefore developed from first principles, using an established pathway and robust framework[28] (*Figure 2*). The prototype STEPWISE intervention aimed to promote autonomous problem-solving around dietary and physical activity choices, with a specific focus on relapse prevention and weight improvement.

The intervention development incorporated four stages, the first three of which are described in this section:

1. foundation of the programme
2. prototype
3. pilot of prototype and incorporation of amendments and adaptation
4. facilitator training.

The programme was developed collaboratively by a team with expertise in the development of obesity and lifestyle programmes, and mental health-care professionals and researchers with specialist knowledge of schizophrenia and psychosis. Following the literature review, we sought the opinion of service users in Sheffield and Leicester between January and September 2014. Three meetings were held in Leicester at a user-led mental health support group; these were attended by 11 people with schizophrenia or other mental health conditions, who provided input to discussions of the suggested prototype curriculum, resources and subsequent iterations. Topics and suggestions were drawn directly from the group, but the researchers also raised issues that they wished to explore with service users. In addition, other service users, carers and investigators provided input at monthly meetings and in one-to-one interviews. We sought advice from expert practitioners with experience of delivering lifestyle management groups for people with psychosis in Salford, UK, and Sydney, Australia. The principles of the constant comparative approach based on grounded theory were used to analyse these meetings.[29]

Six themes emerged from the service users:

1. transportation to and from the venue
2. venue and time
3. level of concentration
4. sessions
5. incentives and motivation
6. accompanying persons.

These are described in *Testing the pilot intervention* and informed the design of the prototype intervention, its content, delivery and logistics.

Development Pathway for Self Management Interventions: From Idea to Research

Explore The Idea
- Literature Review
- Peers
- Target Groups
- Interest Group
- Explore Local & National Agenda
- Service Development Or Research?

Draft Intervention
- Develop theory and philosophy documents
- Curriculum
- Patient Resources
- Educator Resources
- Draft training documents

Feedback/Reflect/Refine
- Participant Feedback
- Educator Feedback
- Observer Feedback
- Resources
- Initial Impact Indicators
- Make Changes
- Record why/what changes have been made

2nd Feedback/Reflect/Refine
- Make Final Changes
- Repeat Process From 1st Pilot
- Draft Assessment Tool

Ready For Research
- Curriculum /Target Group
- Training Programme
- Trained Experienced Educators
- Resources
- Training Programme
- Research Q's
- Desired Outcome
- Intervention Fidelity Process
- Cost Of Intervention
- Research Schedule

8/12 Weeks | 6/8 Weeks | 1/4 Weeks | 8/12 Weeks

Idea! → **Developed Idea to meet a need** → **Intervention Framework** → **Refined Intervention** → **Fit for purpose** → **Training** → **Ready To Go! RCT or Implementation**

6/12 Weeks | 1/4 Weeks | 1/4 Weeks | Dependant on study start and number of Educators required for the trial

Establish A Working Group
- Theories & Philosophies
- Potential Outcomes
- Describes Intervention
- Confirm The Target Group
- Education Delivery Indicators (QD) Observation Tool

1st Pilot
- Structure/Design
- Uptake/Recruitment
- Pilot Curriculum
- Intervention Receipt
- Piloting Resources
- Observe Delivery & Describe
- Recruit Pilot Educators
- Train Pilot educators

2nd Pilot
- 2nd Pilot Of Refined Intervention
- Acquired Feedback (See 1st Pilot)
- Re-train Pilot educators

Training
- Skills & Knowledge Required
- Don't Re invent Wheel
- Scope Existing Training
- What do you want Educators to do/achieve
- Target intervention Behaviours
- Write /Deliver Training
- Trial Resources

Train or Retrain Educators
- Review Training and Refine
- Observe Delivery
- Re -Train in Relation To Intervention Changes

FIGURE 2 The Leicester development pathway for self-management interventions. Reproduced with permission from Dr Sharon Spencer (Dr Sharon Spencer, University of Leicester, November 2017, personal communication).

Prototype

The user group specifically contributed to the intervention format and played an important role in refining the logistics, content and delivery. The Sheffield mental health team and research team also suggested further changes to the prototype curriculum and resources; for example, appropriate supporting tools (incentives) for participants were introduced and the curriculum terminology was adjusted to improve its acceptability.

The prototype intervention comprised four 90-minute core group education sessions, delivered to small groups of six to eight participants over 4 consecutive weeks. A breakdown of each session can be found in *Figure 3*. The curriculum included individual personal stories, taking control of weight, healthier food and drink choices, the relationship between weight and medication, and the relationship between calories and portions and physical activity. The intervention had a written curriculum to ensure consistency and resources in line with its person-centred philosophy. Participants were not 'taught' in a formal way, but instead were supported to discover and work out knowledge for themselves to inform their goals and plans.

Although the intervention was designed to be delivered by two local trained facilitators, the prototype sessions were delivered in Sheffield by the development team and were watched by health-care professionals who had been identified as potential facilitators. Feedback from the developers and potential facilitators confirmed the appropriateness of content and resources, while challenging any assumptions made about style and content. We envisaged that at least one facilitator would be a registered mental health professional, whereas the other would have a professional background as a registered mental health professional, mental health support worker, health-care assistant or similar. Current experience of working with people with mental health issues and knowledge of antipsychotics were key facilitator attributes.

To provide ongoing support, a series of 110-minute follow-up 'booster' sessions were designed to occur every 3 months after the end of the core sessions. Fortnightly support telephone calls from the facilitator team were arranged and appropriate training was given to the facilitators.

Testing the pilot intervention

The pilot testing of the intervention was undertaken in a community setting and comprised a cycle of four cohorts between May and December 2014 (*Figure 4*). Biomedical and lifestyle outcomes were not collected during the pilot. The aims were to:

- test the components of the intervention
- assess the skills and knowledge required from facilitators and so inform the training programme content
- understand the obstacles to, and enablers of, delivering the intervention in a real-world situation in accordance with intervention mapping, as described by Bartholomew *et al.*,[22] and following the Medical Research Council framework for evaluating complex interventions.[30]

The participants were recruited through Sheffield Health and Social Care NHS Foundation Trust Community Mental Health Teams (CMHTs). The eligibility criteria were identical to those proposed for the future RCT (see *Chapter 3*, *Participant selection and eligibility*) to ensure that the intervention would meet the needs of potential trial participants.

Participants were identified during routine clinic appointments and case note review and given brief information about the study. A total of 103 service users with schizophrenia or first episode psychosis were approached by the mental health team, of whom 44 did not meet the eligibility criteria, 16 were non-contactable and 19 declined to participate. Twenty-four people consented to participate, and 20 attended at least one session.

STEPWISE programme

	Session 1	Session 2	Session 3	Session 4	Sessions 5, 6 and 7
Introduction	Introduction (15 minutes)	Introduction (5 minutes)	Introduction (5 minutes)	Introduction (5 minutes)	Introduction (5 minutes)
Your story	Your story (20 minutes)	Sharing stories (20 minutes)	Sharing stories (20 minutes)	Sharing stories (20 minutes)	Sharing stories (20 minutes)
Topic sessions	Topic 1a (35 minutes) Taking control of your weight; healthier drinks	Topic 2a (25 minutes) Taking control of your weight; healthier snacks / Topic 2b (25 minutes) Physical activity	Topic 3a (25 minutes) Taking control of your weight; calories/portions / Topic 3b (25 minutes) Sedentary behaviour	Topic 4a (25 minutes) Taking control of your weight; eating out – challenges and solutions to making choices	Follow-up (50 minutes)
Next steps	Next steps (20 minutes)	Next steps (15 minutes)	Next steps (15 minutes)	Next steps (40 minutes) Your plan	Next steps (15 minutes)
	Supporting tool Water bottle	*Supporting tool* Pedometer	*Supporting tool* Cookery book Food scales	*Supporting tool* Weighing scales Tape measure	

FIGURE 3 Outline of the STEPWISE group sessions. Reproduced from Holt *et al.*[23] This is an Open Access article distributed in accordance with the terms of the Creative Commons Attribution (CC BY 4.0) license, which permits others to distribute, remix, adapt and build upon this work, for commercial use, provided the original work is properly cited. See: http://creativecommons.org/licenses/by/4.0/. The figure includes minor additions and formatting changes to the original text.

Identified as potentially eligible
(*n* = 103)[a]

Not eligible from face-to-face contact
(*n* = 44)
• Engaged in weight management programme, *n* = 2
• Significant alcohol use, *n* = 4
• Tentative diagnosis of mania, *n* = 1
• Current inpatient/too ill, *n* = 3
• Not engaged with service, *n* = 2
• Substance/drug use, *n* = 6
• No weight gain or concern, *n* = 13
• Not taking antipsychotics, *n* = 5
• Out of city, *n* = 2
• New to service, *n* = 1
• < 18 years of age, *n* = 3
• Deaf, unable to participate, *n* = 1
• Does not like groups, *n* = 1

Not contacted
(*n* = 1)
(Reasons unknown)

Attempts to contact by telephone
(*n* = 58)

Unable to contact
(*n* = 15)

Candidate responded
(*n* = 43)

Not eligible
(*n* = 7)
• Alcohol dependence, *n* = 1
• Substance misuse, *n* = 1
• Too ill at present, *n* = 2
• Changed medication within 1 month, *n* = 1
• Bipolar disorder, *n* = 2

Eligible
(*n* = 36)

• Did not attend screening visit, *n* = 1
• Candidate not interested/not willing to participate, *n* = 10
• Unable to attend scheduled course, *n* = 1

Consented
(*n* = 24)

Cycle 1
(*n* = 5)

Cycle 2
(*n* = 3)

Cycle 3
(*n* = 4)

Cycle 4
(*n* = 12)

One could not attend – joined cycle 2

Session attendance[b]
• Week 1, *n* = 2
 (2 DNA – 1 had hospital appointment, 1 unknown)
• Week 2, *n* = 2
• Week 3, *n* = 1
 (1 DNA – unknown reason)
• Week 4, *n* = 2

Session attendance
• Week 1, *n* = 3
• Week 2, *n* = 1
 (2 DNA – 1 unwell, joined cycle 3, 1 unknown)
• Week 3, *n* = 0
 (1 DNA – unknown reason)
• Week 4, *n* = 0

Session attendance
• Week 1, *n* = 4
• Week 2, *n* = 5
 (1 joined from cycle 2)
• Week 3, *n* = 4
 (1 DNA – unknown reason)
• Week 4, *n* = 4

Session attendance
• Week 1, *n* = 11
• Week 2, *n* = 9
 (2 DNA – unknown reasons)
• Week 3, *n* = 8
 (1 DNA – unknown reason)
• Week 4, *n* = 5
 (3 DNA – unknown reasons)

FIGURE 4 Consolidated Standards of Reporting Trials flow diagram for the STEPWISE Intervention Development Study. a, Sheffield Health and Social Care NHS Foundation Trust advised that approximately 100 patients (60 patients at one Community Mental Health Team, 20 at another and 20 at a third Community Mental Health Team) from care co-ordinator lists were prescreened and deemed not to meet the basic inclusion criteria. A further cohort of patients was then prescreened for cycle 4, with a further 64 identified as potentially eligible; b, two participants recruited prior to the first Intervention Development Study cycle were unable to attend but willing to take part in the second cycle; however, they did not take part in the second cycle as a result of returning to work ($n = 1$) and not being contactable ($n = 1$). DNA, did not attend.

The participants attended one of four pilot interventions at a local venue; these comprised the four weekly core sessions, each lasting ≈2 hours, including a refreshment break. Observation notes were taken at each session to supplement feedback from participants and facilitators in order to refine the programme content, resources and delivery as necessary in an iterative process.

Recruitment and reminders for attendance
Recruitment and retention to the first two cohorts were difficult, and novel recruitment strategies, such as the offer of transport, and text and telephone-call reminders, were needed to increase attendance. This led to improved participation in the third and fourth iterations.

Logistical considerations
Participant feedback showed that they valued the intervention and discussion mostly focused on practical ways of facilitating attendance and active engagement. Organisational issues were seen as key factors (e.g. arranging taxis helped participants to arrive in a timely manner, while reducing the anxiety of using public transport). The local mental health venue was described as a convenient and familiar place to reach. The participants reported that the number of sessions was reasonable.

Many people with schizophrenia have altered sleep patterns, which make early-morning appointments difficult, and so the time of the sessions (12.30 for a 13.00 start) was considered to be ideal. During the first cohort, participants struggled to attend on time; this was partly solved by providing taxis, but we also introduced a pre-session healthy lunch. This meant that the participants did not disrupt sessions if they arrived late, and also provided a practical demonstration of how to eat healthily on a limited budget.

Many people with schizophrenia may experience cognitive deficits and limited ability to concentrate over time. To overcome this, we incorporated sufficient and flexible breaks into the pilot intervention.

Sessions
Participants enjoyed the small-group setting, which enabled them to assimilate information more efficiently, share experiences with fellow participants and reinforce existing messages. Participants and facilitators found the resources, such as flipcharts, laminates and booklets, valuable and engaging. Participants commented on the benefit of using the same facilitators throughout the intervention. Contrary to our expectations, participants wished to attend alone and thought that they would not benefit from bringing an accompanying person to the sessions. Participants felt that undertaking the intervention was something they could accomplish on their own and that it would be easier to share information with fellow participants without the presence of people who did not have mental illness.

The use of supporting tools (e.g. samples of low-calorie drinks and snacks, kitchen scales, cookery books and pedometers) reinforced the messages provided to participants about the benefits of participation, improved internal motivation and supported engagement and attendance.

Chapter 3 Evaluation methods

Trial methods

Trial design

We undertook a multicentre, two-arm, parallel-group RCT of the STEPWISE structured lifestyle education programme compared with usual care plus written lifestyle advice in 10 NHS Mental Health Trusts in England. Participants were individually randomised to the STEPWISE programme or usual care. This report is concordant with the Consolidated Standards of Reporting Trials (CONSORT) statement (2010).[31]

Important changes to methods after trial commencement

Trial recruitment commenced on 12 March 2015 (first patient, first visit) and, following this, in response to early observations and feedback from the intervention development study, a number of changes were made to the protocol. The protocol was published[32] and the current version is available via the National Institute for Health Research (NIHR) Journals Library website.[33]

Between the initial Research Ethics Committee approval and study commencement, there were two substantial amendments. These revised the sample size, clarified the eligibility criteria, described the control arm and updated the screening and consent process to ensure that recruitment could take place closer to scheduled intervention sessions.

In March 2015 (substantial amendment 3, protocol version 4.0), following feedback from the intervention development study, the option for participants in the intervention arm to bring along a friend, relative or carer to the intervention sessions was removed. This amendment also added details about referring any concerns or participant risk to the clinical care team. Amendments were made before delivery of the first foundation session (23 April 2015).

In June 2015 (substantial amendment 4, protocol version 5.0), the data collection windows for the Operational Criteria Checklist for Psychotic Illness and Affective Illness (OPCRIT+) and the outcome assessments were increased, to provide more opportunity for sites to follow up participants, allowing for missed appointments.

A further amendment in November 2015 (substantial amendment 5, protocol version 6.0) clarified the use of 'Community Mental Health Teams' in the eligibility criteria. This allowed potential participants within a variety of services, including those stepping down from inpatient to community services, to participate, provided that they could fully implement the learning from the intervention. This amendment also allowed 1 additional week to obtain the fasting blood sample at the 12-month follow-up.

In February 2016 (substantial amendment 6, protocol version 8.0), changes were made to the protocol to allow over-recruitment beyond the initial recruitment target, in order to allow centres to recruit in waves and run intervention groups with sufficient participants.

Participant selection and eligibility

The trial was co-ordinated from the Clinical Trials Research Unit (CTRU) in the Sheffield School of Health and Related Research (ScHARR). Delegated study staff located at participating centres identified and gained consent from potential participants. Eight of the 10 centres [and their principal investigators (PIs)] were involved at the proposal development stage, with two further centres identified through expressions of interest via the NIHR Clinical Research Network.

The trial was promoted within clinical teams and in community areas in which mental health services are delivered. Clinicians used a standardised script to ensure that potential participants received consistent information about the trial. The research team at participating sites worked with clinical teams to identify potentially eligible patients from clinic lists and other caseloads. Self-referrals were also accepted, following the use of information displayed on posters and leaflets.

The study took place within CMHTs, including early intervention services, in 10 mental health NHS trusts in a range of locations, urban and rural, in Sheffield, Leeds, York, Bradford, Greater Manchester, South London, Sussex, Hampshire, Devon, Somerset and Cornwall.

Adults were eligible for inclusion in the study if they:

- were aged ≥ 18 years
- had a diagnosis of schizophrenia or schizoaffective disorder [defined by the *International Classification of Diseases,* Tenth Revision (ICD-10) codes F20 and F25] or first episode psychosis (defined as < 3 years since presentation to the mental health team) using case note review
- were being treated with an antipsychotic
- were able to give written informed consent
- were able and willing to attend and participate in a group education programme
- were able to speak and read English
- had a body mass index (BMI) of ≥ 25 kg/m^2 or were concerned about their weight (in the case of participants from South Asian and Chinese backgrounds, the BMI threshold was reduced to ≥ 23 kg/m^2).

People were excluded from the study if they:

- had a physical illness that could seriously reduce their life expectancy or ability to participate in the trial
- had a coexisting physical health problem that would, in the opinion of the PI, independently affect metabolic measures
- had a mental illness that could seriously reduce their ability to participate in the trial
- had a current pregnancy or were < 6 months post partum
- had a condition associated with significant weight gain (e.g. Cushing syndrome)
- engaged in significant alcohol or substance misuse which, in the opinion of the PI, would limit the patient's ability to participate in the trial
- had a diagnosis or a tentative diagnosis of psychotic depression or mania
- had a primary diagnosis of a learning disability
- were currently (or within the past 3 months) engaged in a systematic weight management programme, to ensure that other programmes did not have an impact on baseline measures.

During the trial, participants were not prevented from joining weight loss or physical activity programmes (intervention arm participants were encouraged to make positive behaviour change); however, any uptake of systematic programmes (other than STEPWISE) was captured at the 3- and 12-month follow-up by asking all participants if they had taken up any other weight management or physical activity programme outside the trial.

All potential participants had a minimum of 24 hours in which to decide whether or not they wished to participate, before attending a consent visit.

The CTRU co-ordinated the follow-up and data collection in collaboration with centres. Participant study data were collected and recorded on study-specific case report forms (CRFs) by site research staff and were entered onto a remote web-based data capture system at each site.

Interventions
All participants received written lifestyle advice on diet, physical activity and alcohol and smoking use before randomisation. Participants were randomised to receive either the STEPWISE education programme or usual care.

Research intervention (STEPWISE education programme)

Participants allocated to the research intervention were contacted by the session co-ordinator and provided with pre-course information, which included an introductory letter and leaflet confirming when and where the sessions would take place and what to expect.

The intervention took place over approximately a 12-month period post randomisation. Participants allocated to STEPWISE received a foundation course of four weekly 2.5-hour (including breaks) group sessions delivered by two trained facilitators. The protocol specified approximately 6–10 participants for each course, to allow for a good group size and to account for likely attrition.

The foundation course was followed by one-to-one support contact lasting for around 10 minutes, approximately every 2 weeks for the remainder of the intervention period. This contact was personalised and was mostly conducted by telephone, although it also took place in person on some occasions. The purpose of the support contact was to discuss participants' progress towards their goals, highlight any issues and try and motivate participants to change their behaviours in line with the group-based session. When participants could not be contacted, a motivational postcard was sent to them to maintain this contact. Support contact was undertaken by a trained facilitator to support behaviour change and obtain feedback from the participant.

Participants were invited to attend 2.5-hour group-based booster education sessions at 4, 7 and 10 months post randomisation. Attendance at all intervention sessions and receipt of support contact were recorded.

Participants who attended education sessions were invited by facilitators to complete a 'session feedback' form at the end of each session. This was completed independently and sealed in an envelope to maintain anonymity. The envelopes were posted directly to the CTRU for data entry. Participants could choose whether or not to include their name on the feedback form, and the aim was to capture a self-report of empowerment and health belief during the intervention.

Between four and six health-care professionals or associated staff at each participating centre received facilitator training to deliver the STEPWISE intervention. This training covered the core DESMOND philosophy (3 days), specific content and delivery of the STEPWISE programme (1 day) and the content and delivery of booster sessions (1 day).

Control arm

Participants allocated to the control arm received treatment as usual (TAU), enhanced by the provision of written lifestyle advice. There is known variability in the provision of physical health care, despite NICE guidelines on the treatment and management of schizophrenia regarding healthy eating and physical health.[14] To standardise usual care in both groups as far as possible, participating centres provided printed guidance to all participants (regardless of allocation) before randomisation on the risk of weight gain and lifestyle advice, regarding diet, physical activity, smoking and alcohol use, when appropriate.

Usual care

It is appropriate in pragmatic trials for the comparison intervention to involve 'usual practice', offering study sites leeway in deciding what that should involve.[34] As the content of usual care can influence effect size,[35] we undertook a survey of usual care at the participating centres at two time points. The methods for this exercise have been reported previously,[36] but, in brief, sites were surveyed on their current practices regarding healthy eating and physical activity programmes offered to people with schizophrenia. The survey was based on current NICE guidance[14] and included questions about any trust-offered healthy eating and physical activity programmes, what discussions take place with patients before antipsychotic initiation, the availability of smoking cessation support and how physical health reviews are completed, including what measures are reviewed and how often.

Measurement of outcomes

Following consent but before randomisation, research staff completed CRFs for each participant, which covered medical and psychiatric history, demographics and current medication information (*Table 2*). All assessments and questionnaires were undertaken either at the participant's home or in the NHS trust. A fasting blood sample was taken, as well as measurements of vital signs and anthropometry. Baseline self-report instruments were completed, with research staff encouraged to read questions aloud to

TABLE 2 Trial outcome measures

Outcome measure	Time point			
	Pre-baseline	Baseline	3 months	12 months
Eligibility criteria assessed by the clinical care team	✗			
Medical history		✗		
Psychiatric history		✗		
OPCRIT+[37]		✗		
Renal function		✗		✗
Hepatic function		✗		✗
Height (to calculate BMI)		✗		
Weight		✗	✗	✗
Waist circumference		✗	✗	✗
Physical activity [7-day wrist-worn GENEActiv (Activinsights, Kimbolton, UK) accelerometer]		✗	✗	✗
Adapted DINE questionnaire[38]		✗	✗	✗
Blood pressure		✗	✗	✗
Fasting glucose		✗		✗
Lipid profile		✗		✗
Glycated haemoglobin		✗		✗
EQ-5D-5L[39]		✗	✗	✗
SF-36[40]		✗	✗	✗
B-IPQ[41]		✗	✗	✗
BPRS[42]		✗	✗	✗
Smoking status		✗	✗	✗
CSRI[43]		✗	✗	✗
Changes in medication (dose and side effects)		✗	✗	✗
PHQ-9[44]		✗	✗	✗
Use of weight loss programmes			✗	✗
Adverse events			✗	✗
Session feedback (intervention only; each group session)		✗		

B-IPQ, Brief Illness Perception Questionnaire; BPRS, Brief Psychiatric Rating Scale; CSRI, Client Service Receipt Inventory; DINE, Dietary Instrument for Nutrition Education; EQ-5D-5L, EuroQol-5 Dimensions, five-level version; PHQ-9, Patient Health Questionnaire-9; SF-36, Short Form questionnaire-36 items.
Note
Adapted from Gossage-Worrall *et al.*[32] This article is distributed under the terms of the Creative Commons Attribution 4.0 International License (http://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided you give appropriate credit to the original author(s) and the source, provide a link to the Creative Commons license, and indicate if changes were made. The Creative Commons Public Domain Dedication waiver (http://creativecommons.org/publicdomain/zero/1.0/) applies to the data made available in this article, unless otherwise stated.

participants, with all available answer options, to ensure understanding. Participants were provided with a wrist-worn accelerometer to wear 24 hours per day for 7 days following the visit.

Additional information, such as medication details and details of hospital admissions, was obtained and/or verified using the patient's medical notes. At both the 3- and the 12-month follow-up visits, research staff who were masked to treatment allocation confirmed medication information with participants, particularly doses and side effects of antipsychotic medication. They took measurements of blood pressure, weight and waist circumference (and a fasting blood sample at 12 months only) and provided the participant with a wrist accelerometer to wear for the next 7 days. Participants were asked to complete the same questionnaires as at baseline, with the addition of a form to capture the uptake of any weight loss programmes outside the STEPWISE trial. The follow-up windows at 3 and 12 months were defined as minus 2 weeks and plus 4 weeks to allow time for missed and rearranged appointments.

Biomedical measures
The biomedical outcomes were:

- Weight outcomes – change in weight, the proportion of participants who maintained or reduced weight, percentage change in weight, waist circumference and BMI. Standard operating procedures specified how to measure body weight (e.g. light clothing, shoes off) using the Class III approved Marsden 430-C portable scales (Marsden Weighing Machine Group Limited, Rotherham, UK) to the nearest 0.1 kg; height (e.g. standing tall, feet hip-width apart and head level) using the Class I approved Marsden HM-250P stadiometer (Marsden Weighing Machine Group Limited, Rotherham, UK) to the nearest 1 cm; and waist circumference (e.g. tape lying flat and level, taut but not tight) using the Class I approved Seca 201 tape measure (Seca, Birmingham, UK) to the nearest 0.1 cm. Participants who provided 12-month weight data in accordance with the protocol received a £20 shopping voucher.

- Vital signs and laboratory measurements:
  - blood pressure (average of three measurements) and pulse, measured by electronic sphygmomanometer in the non-dominant arm after 5 minutes' rest
  - fasting glucose, lipid profile and glycated haemoglobin (HbA_{1c}) at baseline and 12 months only (all blood samples were analysed by local laboratories).

Physical activity
Physical activity was assessed by wrist-worn accelerometer (GENEActiv, Activinsights Ltd, Kimbolton, UK). Participants were asked to wear the accelerometer on their non-dominant wrist continuously (i.e. 24 hours per day) for 7 days and data were derived using the approach reported in da Silva *et al.*[45] The GENEActiv.bin files were analysed with R-package GGIR, version 1.5 (Cran-R Project, the Netherlands).[28,29] Signal processing in GGIR includes the following steps:

- autocalibration, using local gravity as a reference[28]
- detection of sustained abnormally high values
- detection of non-wear
- calculation of the average magnitude of dynamic acceleration (i.e. the vector magnitude of acceleration corrected for gravity [Euclidean norm minus one *g* (ENMO)] as:

$$ENMO = \Sigma\sqrt{x^2 + y^2 + z^2} - g,$$ (1)

over 5-second epochs, with negative values rounded up to zero.

Files were excluded from all analyses if the post-calibration error was $> 0.02\ g$[30] or < 16 hours of wear time as recorded by either monitor during the 24-hour day of interest. Detection of non-wear has been described in detail previously.[29] In brief, non-wear is estimated based on the standard deviation (SD) and value range of each axis, calculated for 60-minute windows with 15-minute moving increments. If for at least two out of the three axes the SD is < 13 mg (milligravity) or the value range is < 50 mg, the time window is classified as non-wear.

The average magnitude of dynamic wrist acceleration (ENMO) and time accumulated in moderate or vigorous physical activity (MVPA) were calculated. The threshold for determining MVPA was ≥ 100 mg.

Four measures were taken:

1. mean acceleration calculated per day
2. MVPA based on a 5-second epoch setting (i.e. total unbouted MVPA)
3. MVPA based on a 5-second epoch setting and a bout duration of 5 minutes, inclusion criteria based on $> 80\%$
4. MVPA based on a 5-second epoch setting and a bout duration of 10 minutes, inclusion criteria based on $> 80\%$.

Each of the above was calculated for weekdays (provided data were available for at least 3 of the 5 days), weekends (provided data were available for at least 1 day) and all days (when data were available for at least 4 of the 7 days).

Lifestyle factors

Three lifestyle measures were collected. These were the adapted Dietary Instrument for Nutrition Education (DINE) questionnaire,[38] smoking status and use of weight loss programmes:

- The adapted DINE questionnaire measures diet on six items – fibre intake, fat intake, unsaturated fat intake, sugar intake, alcohol intake and meal type. Scores and ratings were calculated only when all constituent items had been reported for the particular item.
- Smoking status was measured by the number and percentage of participants who smoke, smoking category [light (< 10 cigarettes per day), moderate (10–19 cigarettes per day) or heavy (≥ 20 cigarettes per day)], interventions offered to aid smoking cessation and interventions taken to aid smoking cessation.
- Use of weight loss programmes (follow-up only); the number and percentage of participants who reported enrolling in any weight loss programme.

Patient-reported outcome measures

Four patient-reported outcome measures were collected:

1. EuroQol-5 Dimensions, five-level version (EQ-5D-5L) health utility,[46] comprising a health state and thermometer scale. Higher scores indicate a better health state.
2. The Short Form questionnaire-36 items (SF-36),[47] from which eight domains of quality of life (QoL) were derived. Higher scores indicate a higher QoL.
3. The Patient Health Questionnaire-9 (PHQ-9),[44] a measure of depressive symptoms. Higher scores indicate more severe depressive symptoms.
4. The adapted Brief Illness Perception Questionnaire (B-IPQ),[41] a measure of illness perception. Higher scores reflect a more threatening view of the obesity.

Clinician-assessed outcome measure

Participants were assessed using the Brief Psychiatric Rating Scale (BPRS), a clinician-rated measure that evaluates the psychopathology of patients with schizophrenia.[42] Higher scores indicate greater psychiatric concern.

The OPCRIT+ was completed by the research team, using case note review, within 10 weeks of the baseline visit. This was to provide comparable baseline characteristics for all participants across the study. The protocol allowed baseline fasting blood samples and accelerometry data to be collected after randomisation when recruitment occurred close to a scheduled intervention course.

Cardiovascular and diabetes mellitus risk

The 10-year cardiovascular risk was calculated using the Framingham Cardiovascular Risk Score.[48] An analysis using a second cardiovascular risk score for people with severe mental illness (PRIMROSE)[49] was planned but not used, as a problem emerged with the algorithm during the analysis. The 10-year type 2 diabetes mellitus risk was calculated by the Leicester score.[50]

Derivation of outcome measures

The EuroQol-5 Dimensions (EQ-5D) tariff was scored using the EQ-5D-5L for UK population norms;[51] no score was calculated if any of the five items were missing. The eight subscales of the SF-36 were calculated as per McHorney *et al.*;[40] subscores were calculated when at least half of the questions within the domain had been answered. When all eight domains were completed, the aggregate physical and mental component scores were calculated. The adapted B-IPQ was scored by summing the responses to items into a single score[41] if at least six of the eight questions were answered. The BPRS was scored by summing up the responses into a single score[42] and was calculated if at least 14 of the 18 items had been answered.

Sample size

The sample size calculation was based on data from two sources, both of which assessed behavioural interventions for weight loss in people prescribed antipsychotics for schizophrenia. First, a systematic review undertaken by Das *et al.*[52] examined both randomised and non-randomised controlled trials, and reported between-group differences of 1.5–6 kg (SD ≈5 kg). Data on overweight and obese UK patients with severe mental illness from a second study also contributed to the sample size calculation. A total of 51 people with schizophrenia were followed up for at least 1 year, and the weight change reported was 7.7 kg (SD 6.5 kg).[53]

The sample size used in STEPWISE aimed to detect a difference of 4.5 kg, which is clinically meaningful (average ≈5% reduction in body weight)[54] and also appears to be compatible based on previous work. A conservative estimate of a SD of 10 kg, 95% study power and a two-sided significance level of 5% was assumed, meaning that 130 participants per intervention arm (260 participants in total) were required to detect a minimum clinically important difference of 4.5 kg.

Owing to the group nature of the intervention, it is possible that the outcomes of participants within the same group may be correlated. Therefore, an average group size of seven participants was assumed, with an intraclass correlation of 5% in the intervention arm. For this reason, the sample size was inflated by a design effect of 1.3 in the intervention arm, which gives revised sample sizes of 169 participants in the intervention arm and 130 participants in the control arm (299 in total).

To ensure a 1 : 1 allocation, 158 participants were required per arm to reproduce this power. Assumptions were made for a conservative dropout rate of 20%, which is higher than that observed in similar studies,[55] giving a final sample size of 198 participants per trial arm. This equates to 40–50 participants at each centre, with 20–25 of these receiving the intervention in up to four groups per site.

Randomisation

Sequence generation
The randomisation list was generated using the CTRU's web-based system, which provided central randomisation and ensured that the study team was blinded to the allocation. The list was generated using permuted blocks of random sizes to allocate participants to either TAU plus the STEPWISE lifestyle education programme or TAU alone in a 1 : 1 ratio, stratified by site and time since the start of antipsychotic medication (< 3 months or ≥ 3 months). When the exact duration was unknown, an approximate duration was considered to be acceptable for the purposes of randomisation.

Implementation
After the baseline assessments were completed and consent was provided, participants were randomised using the STEPWISE randomisation system. Once randomised, an unblinded member of the site research team informed the participant and their general practitioner (GP) of the treatment allocation.

Blinding
All research team members performing outcome assessments were blind to treatment allocation. Blind (or suspected) breaks were recorded. Owing to the nature of the intervention, participants were not blinded.

Ethics aspects
The study received a favourable opinion from the National Research Ethics Committee, Yorkshire & the Humber – South Yorkshire on 4 February 2014 (reference 14/YH/0019).

Patient and public involvement
Angela Etherington (a person with severe mental illness and experience of taking antipsychotic medication) and David Shiers (the carer of a family member with schizophrenia) were involved in the design of the study and the intervention, management meetings, the qualitative research analysis and the drafting of the report. They reviewed, made changes to and approved the final lay summary.

Statistical methods

Outcome measures

Primary outcome measure
The primary end point of the STEPWISE trial was the change in weight (kg) at 12 months after randomisation.

Secondary outcome measures
Secondary outcomes included biomedical measurements, physical activity, dietary components and psychosocial factors, including QoL, health beliefs and cost-effectiveness. All secondary outcome measures were assessed at baseline and after 3 and 12 months (except when stated), to measure if there was an effect at the end of the intervention and, if so, whether or not this was sustained over the longer term.

Analysis of weight change
The primary objective (weight change at 1 year post randomisation) was assessed by fitting a marginal generalised estimating equation (GEE) model using robust standard errors and an exchangeable correlation structure. The difference between intervention and control arms was adjusted for baseline weight, site and years since antipsychotic medication initiation. The intraclass correlation coefficient (i.e. the 'cluster' term)

was derived from the correlation matrix of the GEE model. The following preplanned sensitivity analyses were undertaken:

- alternative covariates (in which any imbalanced baseline characteristics were added into the GEE model)
- alternative model structure (multilevel model in place of the GEE to estimate the cluster effect)
- alternative assumptions for missing data.

The last of these analyses used approaches proposed by von Hippel,[56] Carpenter *et al.*[57] and White *et al.*[58] The complete-case analyses were augmented with a reanalysis assuming a missing-at-random (MAR) mechanism, achieved by incorporating all baseline covariates that were associated with the probability of missing weight at 12 months and/or with weight change among those who were followed up; these included baseline demographics, disease characteristics, recruiting site, treatment group, weight, BPRS score, B-IPQ score and physical domains of the SF-36 at baseline and 3 months.

The first model incorporated baseline measures as covariates, following which the treatment effect was re-estimated (model MAR 1). Following this, predictive mean matching multiple imputation via chained estimation incorporated all available baseline and 3-month values to impute missing 12-month weight using the original model covariates (model MAR 2). Thereafter, the sensitivity to missing not at random (MNAR) was assessed by adding a range of fixed quantities (delta) to the MAR prediction; for example, delta = 1 corresponds to the assumption that an individual with no 12-month data has a weight change of 1 kg more than predicted. The values of delta used ranged from –5 to + 5 kg and included different values of delta for the two treatment groups.

The treatment comparison was calculated in the following preplanned subgroups:

- uptake of therapy (non-attender; attended one or two foundation sessions; attended three or four foundation sessions but no booster sessions; attended at least three foundation sessions and one booster session)
- recruiting centre
- clinical diagnosis (first episode vs. other diagnoses)
- time since starting antipsychotic medication ($\leq$ 12 months, > 12 to $\leq$ 24 months and > 24 months)
- BMI ($\leq$ 25 kg/m^2, > 25 to $\leq$ 30 kg/m^2, > 30 to $\leq$ 35 kg/m^2, > 35 to $\leq$ 40 kg/m^2 and > 40 kg/m^2)
- principal reason for dietary concern, as assessed by the B-IPQ.

Analysis of other outcomes

Other outcomes were analysed using a GEE model, with the covariates being treatment group, site, years since antipsychotic medication initiation and the baseline measurement of the respective outcome.

General considerations

A comprehensive statistical analysis plan was developed before the database freeze and while the statistician was blinded to treatment allocation. Data were reported and presented in accordance with the revised CONSORT statement.[31,59] Analyses were performed on an intention-to-treat basis, unless otherwise stated. Analyses of outcome in relation to protocol compliance were undertaken by looking at the level of course attendance (a subgroup analysis in *Analysis of other outcomes*) and by complier-average causal effect (CACE), using two-stage least squares regression; the latter defined compliance as attendance of at least one foundation course.

All statistical tests were two-tailed at a 5% significance level and CIs were two-sided, with 95% intervals. No adjustment was made for multiplicity, but the number of outcome measures used necessitates cautious interpretation of statistical significance. All analyses were performed in the Stata® version 14.2 (StataCorp LP, College Station, TX, USA) statistical software, using the user-written Stata package *rctmiss* for the first MNAR model.[60]

Process evaluation

Overview

The process evaluation was undertaken 'to explain discrepancies between expected and observed outcomes, to understand how context influences outcomes, and to provide insights to aid implementation'.[30] Specifically, we investigated whether or not (1) treatment is consistent with the underpinning behaviour change theories (treatment theory or theory of change) and (2) contextual factors affected implementation. The process evaluation used a pipeline logic model, showing causal links between resources, activities and outcomes, integrating the National Institutes for Health Behaviour Change Consortium (NIHBCC)'s approach to treatment fidelity[24] and a modified version of Linnan and Steckler's framework for process evaluation.[61] We described context qualitatively and took a mixed-methods approach to characterising recruitment, reach, dose delivered/received and fidelity both qualitatively and quantitatively, with triangulation between data sources.[62] Interviews were held with intervention designers, health professionals and RCT participants, and the analyses were combined with RCT data and quantitative fidelity data.

Researchers

The qualitative researchers, Rebecca Gossage-Worrall, a female graduate sociologist [Master of Arts (MA); Research Associate], and Daniel Hind, a male graduate anthropologist [Doctor of Philosophy (PhD), Reader], had 8 and 10 years' experience of interviewing, respectively. No relationship was established with any participant outside or before the interview. The interview purpose was explained to participants twice, at consent to trial and at interview. Two facilitators had a prior relationship with Rebecca Gossage-Worrall (through their study research role) before participating in the interviews. Daniel Hind knew two intervention developers prior to interview via project meetings.

Theoretical and thematic framework

Rationale and worldview[63]/epistemology[64]

We incorporated qualitative research to understand the implementation of, and response to, the intervention,[65–67] to propose causal pathways to success or failure.[65–68] However, our rationale was primarily pragmatic rather than explanatory;[69] we were pursuing a basis for 'organising future observations and experiences'[70] by 'investigating conceivable practical consequences'[71] of future decisions, rather than advancing, building or testing social science theory.[68,72]

Research design[63]/methodology[64]/approach[73]

We used a single-case design,[74] with the unit of analysis variably at the participant level ($n = 24$ participants) and at the level of the experimental intervention programme ($n = 20$ facilitator interviews). In participant case studies, the embedded units of analysis were (1) post-course interview and (2) quantitative CRFs, especially weight at 0, 3 and 12 months.

Theory

We used the International Classification of Functioning (ICF) as a conceptual framework for describing the schizophrenia-specific context for implementation.[75,76] We used an a priori framework, based on similar studies,[77,78] to inform the topic guide for interviews with participants (*Table 3*). Topic guides for interviews with health professionals were designed around the normalisation process theory (NPT).[80–83] We used the theoretical domains framework (TDF)[84] to characterise stakeholder understandings of the intervention. Codes from the TDF were later mapped to constructs from the principal theories underpinning the STEPWISE intervention: Bandura's self-efficacy theory,[85] the self-regulation theory of Leventhal *et al.*[86] and Marlatt and George's relapse prevention model.[87] We used the NIHBCC's framework for understanding intervention fidelity[79] and the framework of Sekhon *et al.* for understanding the acceptability of health-care interventions.[88]

TABLE 3 Example questions derived from the a priori framework

A priori theme	Example interview question
Acceptability[77,78]	• How did you find the STEPWISE programme? • Was there anything in particular that you liked about it? • Was there anything in particular that you did not like about it? • How easy or difficult would it be to pay for the travel to the sessions? • How long were the sessions? Was that OK? How many sessions did you attend? (Probe: if sessions were missed, why?) • How do you feel now that it is the end of the weekly course?
Being in a group[77,78]	• How many people were in your group? (Probe: was this number OK?) • How easy or difficult did you find talking in the group? (Prompt: talking about weight, experience of attending other weight management programmes and how they differ)
Presentation of content[78]	• Did you feel it got the balance right in terms of talking about both diet and physical activity? • What did you think of the people who led your group?
Changes in behaviour[77,78]	• Did you receive anything to help you to put into practice what you learned? (Prompts: water bottle; scales; printed materials) • How useful or not were these items?
Processes of change[78]	• Did the programme meet your needs?
Types of interventions[78]	• Did you feel it got the balance right in terms of talking about both diet and physical activity?
Fidelity[79]	• Did you have any of the one-to-one contact with your facilitator?

We developed a programme theory to identify essential elements for the successful replication and causes of failure in the contracts, actions, interactions and emergent relationships between people and organisations that surround the STEPWISE intervention.[89–91] The programme theory development was deductive, through literature review and by articulating mental models in discussion with the LDC team, and inductive, through interviews with participants and professionals.[92] To illustrate how sequences of events were to bring about desirable outcomes, as per the programme theory, we developed a logic model (*Figure 5*).[93,94]

Participant selection and setting

Consent for participant interviews was requested, face to face, at the time of consent to the RCT (when participants specified a preferred method of approach) and reconsented immediately before interview. The majority of participants were approached by telephone. Professionals were approached directly by telephone, e-mailed the information sheet and consented by telephone; intervention designers were approached during project meetings and by e-mail. The RCT intervention arm participants were purposively sampled (*n* = 24) from those consenting and allocated to the intervention (*n* = 188) to reflect different study centre, gender and age (*Table 4*). A total of 63 participants (34%) were sampled, of whom 22 (35%) were non-responsive, despite a minimum of three attempts to contact. Ten participants declined when invited to participate, one declined at (re-)consent and six consented but did not attend the appointment. Forty professionals were purposively sampled to reflect differences in site, occupation, sex and prior group facilitation characteristics (derived from a short survey after completing facilitator training) for invitation to study, of whom 20 were interviewed (*Table 5*); none formally declined, but many left their employment or were non-responsive, or it became unnecessary to interview them because of accrual of the target sample. All those involved with the intervention design were interviewed. All interviews were conducted by telephone.

| Resources | Activities | Immediate outcomes | Intermediate outcomes | Longer-term outcomes |

STEPWISE programme
• Infrastructure
• Trainers
• Their mentors/managers

STEPWISE programme Mentors frequently assess the competency of trainers

Quality of STEPWISE training maintained

Training course materials and venue

Trainers train and periodically assess fidelity of NHS trust-based group facilitators

Sessions delivered in line with STEPWISE philosophy ('fidelity')

Trusts can monitor patient-important outcomes

Reduced:
• weight
• depression
• inappropriate service use
• blood pressure
• BMI
• incidence of smoking

Increased:
• physical activity
• health-related quality of life

Improved:
• nutrition
• enactment of health behaviours

Trusts sustain STEPWISE Uptake sustained

• Health professionals motivated to become STEPWISE facilitators (ideally experienced in group facilitation)
• Appropriately resourced co-ordinator
• Buy-in from NHS trust chief executive and gatekeepers

Programme management (including identification of staff, booking rooms)

Attendance at all foundation and booster sessions; one-to-one telephone support sessions with demonstrable in-session 'receipt' of behaviour change content ('dose received')

Cost-effectiveness demonstrated. NICE recommend the STEPWISE programme as part of care pathway

STEPWISE course materials: venue, leaflets, patient handbook, refreshments, travel costs

Gatekeepers actively refer people

4 × weekly foundation sessions and 3 'booster' sessions; one-to-one telephone support calls made ('dose delivered')

Other trusts adopt the STEPWISE programme

People with schizophrenia motivated to attend the course

'Case' management (booking people on course, sending letters, follow-up)

Eligible people invited to attend the STEPWISE programme ('reach')

Obesity, type 2 diabetes mellitus and cardiovascular events reduced in population of people with schizophrenia

FIGURE 5 Logic model for the implementation of the STEPWISE intervention.

TABLE 4 Important characteristics of the qualitative sample (all intervention participants)

ID	Sex	Age (years)	Diagnosis[a]	Ethnicity	BPRS score	Sessions		Weight in kg			Weight change in kg			Interview took place after (session)
						Foundation	Booster	0 months	3 months	12 months	0–3 months	3–12 months	0–12 months	
Clinically important weight loss over 12 months														
S03/Q06	M	35	F20	White British	34	4	3	115.5	111.7	98.3	−3.8	−13.4	−17.2	Booster 2
S01/Q01	F	40	F20	African	27	3	2	106.7	101.0	94.0	−5.7	−7.0	−12.7	Foundation
S08/Q05	F	28	F25	White British	41	4	3	103.4	104.9	94.1	1.5	−10.8	−9.3	Booster 1
S04/Q02	F	33	FEP	African	34	4	0	92.2	93.4	86.1	1.2	−7.3	−6.1	Foundation
S06/Q01	M	23	F20	White British	27	3	2	92.7	92.6	87.5	−0.1	−5.1	−5.2	Foundation
S01/Q05	M	40	F20	White British	24	4	2	110.4	105.4	105.2	−5.0	−0.2	−5.2	Foundation
S02/Q04	F	40	F25	White British	31	4	3	74.0	71.0	69.3	−3.0	−1.7	−4.7	Booster 2
Weight loss that is not clinically important														
S10/Q03	F	39	F20	White British	23	3	3	110.8	108.2	107.4	−2.6	−0.8	−3.4	Booster 1
S04/Q09	M	48	F20	White British	47	3	1	70.1	71.9	68.7	1.8	−3.2	−1.4	Foundation
S09/Q04	M	43	F20	White British	25	4	2	125.1	110.0	123.7	−15.1	13.7	−1.4	Foundation
S09/Q02	F	49	F25	White British	21	4	3	105.5	104.4	104.2	−1.1	−0.2	−1.3	Foundation
S08/Q06	F	44	F20	White British	28	2	2	92.0	93.6	90.8	1.6	−2.8	−1.2	Foundation
S01/Q04	M	43	F20	White British	33	3	3	96.7	97.0	96.6	0.3	−0.4	−0.1	Booster 1

TABLE 4 Important characteristics of the qualitative sample (all intervention participants) (*continued*)

ID	Sex	Age (years)	Diagnosis[a]	Ethnicity	BPRS score	Sessions		Weight in kg			Weight change in kg			Interview took place after (session)
						Foundation	Booster	0 months	3 months	12 months	0–3 months	3–12 months	0–12 months	
Weight gain that is not clinically important														
S05/Q03	F	54	F25	White British	53	4	3	92.4	90.0	92.9	−2.4	2.9	0.5	Foundation
S06/Q02	M	34	FEP	White British	32	3	2	121.8	126.0	123.9	4.2	−2.1	2.1	Booster 1
S03/Q01	F	36	F20	Bangladeshi	24	4	2	101.5	103.3	103.7	1.8	0.4	2.2	Foundation
S04/Q10	M	19	FEP	White British	36	2	0	84.6	83.9	87.7	−0.7	3.8	3.1	Foundation
S08/Q09	F	31	F25	White British	23	4	1	92.4	96.4	95.5	4.0	−0.9	3.1	Foundation
S09/Q01	M	54	F20	White British	29	3	3	86.3	87.3	90.4	1.0	3.1	4.1	Foundation
Clinically important weight gain														
S04/Q12	M	30	FEP	Indian	26	4	3	120.0	124.3	125.5	4.3	1.2	5.5	Foundation
S07/Q06	M	25	FEP	White British	34	3	2	131.6	140.0	142.9	8.4	2.9	11.3	Foundation
S04/Q08	F	32	FEP	White British	44	4	3	126.2	139.8	155.9	13.6	16.1	29.7	Booster 1
Qualitative participants without weight data														
S04/Q06	F	25	FEP	White British	34	4	0	86.0	94.0	ND	8.0	ND	ND	Booster 1
S06/Q06	M	21	FEP	White other	39	3	2	91.3	79.0	ND	−12.3	ND	ND	Booster 1

F, female; ID, identification; M, male.
a   FEP, first episode psychosis; F20, schizophrenia; F25, schizoaffective disorder; ND, no data.

TABLE 5 Characteristics of the qualitative sample (facilitators)

| ID | Professional category | Education | Worked in | | | | Groups facilitated | Confidence in skills (0 = low; 5 = high) |
| | | | Mental health | | Physical health | | | |
			Years	Months	Years	Months		
S01/F02	Support worker	City and Guilds of London Institute	29	0	ND	ND	1	4
S01/F04	Mental health nurse	PG degree	8	0	0	0	0	3
S02/F02	Healthy living advisor	UG degree	ND	ND	ND	ND	10	4
S02/F03	Physiotherapist	UG degree	2	4	4	3	10	4
S02/F06	Dietitian	UG degree	3	4	3	4	99	4
S03/F02	Occupational therapist	UG degree	5	0	0	0	24	4
S03/F04	Mental health nurse	UG degree	11	4	ND	ND	ND	5
S03/F05	Community development	UG degree	8	10	3	11	15	4
S04/F02	Support worker	No data	38	4	14	ND	ND	4
S04/F03	Clinical studies officer	PG diploma	6	2	0	0	3	4
S05/F02	Mental health nurse	PG degree	17	0	17	0	2	5
S06/F01	Research assistant	PG degree	2	0	ND	ND	0	3
S06/F04	Mental health nurse	Diploma (college)	24	11	0	0	1	4
S06/F05	Mental health nurse	PG diploma	7	8	ND	ND	0	3
S07/F05	Mental health nurse	UG degree	7	3	0	0	0	4
S08/F03	Mental health nurse	UG degree	26	9	ND	ND	0	4
S08/F05	Occupational therapist	UG degree	20	0	ND	ND	ND	4
S09/F01	Mental health nurse	Diploma (college)	25	4	ND	ND	0	3
S09/F03	Occupational therapist	UG degree	6	7	ND	ND	5	4
S09/F04	Pharmacy technician	BTEC degree in Pharmaceutical Science	8	0	ND	ND	1	3

BTEC, Business and Technology Education Council; ID, identification; ND, no data; PG, postgraduate; UG, undergraduate.

Data collection

Semistructured interview guides for participants (see *Appendix 1*) and professionals (see *Appendix 2*) were pilot-tested with the relevant project team members. No topic guide was used for the unstructured interviews with intervention designers, although sections from the behaviour change wheel,[95] the logic model and the NIHBCC framework[24] were used as prompts. Interviews were recorded on an encrypted digital recorder and field notes were made during and after the interview. The median (range) length of the interviews was 18:57 minutes (13:06–30:33 minutes) for participant interviews, 46:13 minutes (29:29–76:32 minutes) for facilitator interviews and 39:20 minutes (43:39–64:00 minutes) for intervention designer interviews. Data saturation was achieved in the participant, professional and intervention designer data sets. No repeat interviews were carried out and transcripts were not returned to participants for comment/correction.

Data analysis

Two coders (RG-W and DH) coded participant interviews systematically in NVivo version 11 (QSR International, Warrington, UK) to behaviour change theory, intervention functions, theoretical domains[95] and dimensions of acceptability,[88] as well as opportunistically to the NIHBCC framework[79] (see *Table 6*) and logic model constructs (see *Figure 5*). Staff interviews were coded systematically to NPT constructs and opportunistically to the NIHBCC framework and logic model constructs. Developer interviews were coded systematically to intervention functions, logic model and NIHBCC framework constructs (see *Table 6*).

Fidelity assessment

Leicester Diabetes Centre staff monitored the fidelity of intervention delivery through direct observation of sessions, using two instruments. First, the STEPWISE Core Facilitator Behavioural Observation Sheet assesses the relative presence or absence of 35 behaviours in six domains: non-judgemental engagement of participants (five items); eliciting and responding to emotions/feelings (two items); facilitating reflective learning (eight items); behavioural change, planning and goal-setting (nine items); overall group management (nine items); and other behaviours (two items). Second, LDC staff objectively assessed participant–educator interaction during observation visits by means of the DOT (DESMOND Observation Tool). The coder sat at the back of the room, with a compact disc playing in a headphone, from which a beep sounded every 10 seconds, whereupon the coder recorded whether an educator or a participant was currently talking at that point. Silence, laughter or multiple conversations were classed as 'miscellaneous'. In self-management programme research, a link has been proposed between less facilitator talk and a more effective participant receipt of the education process, defined as a less didactic/more facilitative approach.[96] The national and local infrastructure available for quality control and mentoring in education programmes such as DESMOND was not available for STEPWISE, so feedback of observations in pursuit of accreditation was conducted. Other steps to ensure intervention fidelity are described in *Table 6*.

Triangulation protocol

Different methods and informants were used and a formal framework was employed for comparison of the findings to comprehensively address different questions, increase confidence in findings and provide a basis for feedback from participants and professionals on the project team.[97] No priority was granted to either quantitative or qualitative methods, which were used concurrently to assess the intervention. A modified triangulation protocol[62] was employed for the methodological triangulation of data sets, in five stages:

1. Data sets were reviewed to compare for presence and examples ('sorting') of logic model constructs.
2. The level of convergence between data types was coded for each of the 22 logic model components as 'agreement' (full interpretive agreement between data sets); partial agreement (some disagreement within/between data sets); silence (a logic mode component covered by only one data set); and dissonance [disagreement between data sets ('convergence coding')].
3. The global level of convergence was characterised ('convergence assessment').
4. Differences in the data set contribution to the case study were summarised ('completeness comparison').
5. The triangulated results were shared and points of disagreement were discussed with stakeholders at a face-to-face meeting on 14 July 2017 ('feedback'), with changes in interpretation being incorporated when supported by the data. A formal comparison of researcher coding was not conducted, owing to time constraints and a rapidly evolving analysis strategy.

TABLE 6 Strategies within the STEPWISE programme that were intended to ensure fidelity

Goal	STEPWISE fidelity strategies
Design	
Ensure the same treatment dose within conditions	• Theory-based scripted programme defined in the protocol • Specified (and recorded) fixed number, duration, frequency and mode of delivery of education sessions. Deviations logged
Ensure an equivalent dose across conditions	Not applicable (no active control)
Plan for implementation setbacks	• Providers ensured a pool of (a minimum of four) trained facilitators and attrition track (with additional training needs met) • Test intervention piloted and changes in design incorporated
Training	
Standardise training	• Standardised training programme • Written facilitator training manual and materials • Structured practice and (expert) trainers model the style of delivery • Multiple providers trained together
Ensure provider skill acquisition	• Role playing (trainees 'have a go') • Trained to (self-) reflect on performance and make changes
Minimise 'drift' in provider skills	Not applicable (no benchmark established)
Accommodate provider differences	• Facilitator role defined. Providers advised to ensure that at least one facilitator had adequate clinical skills • Facilitator characteristics (experience of leading groups, level of education and professional background) collected at training • All providers received training, and more-experienced providers gave informal support to less-experienced providers
Delivery	
Control for provider differences	• Session feedback invited on non-specific treatment effects (e.g. credibility of facilitator) • Qualitative interview, including perceptions of the intervention at the end of the study • Sessions were observed by intervention developers, who noted any effects
Reduce differences within treatment	• Written treatment manual and standardised resource list (e.g. food models and samples for each session)
Ensure adherence to treatment protocol	• Facilitator self-reflection on content/delivery • Central team monitored treatment dose delivered through attendance registers • Providers monitored intervention delivery and adherence to varying degrees (e.g. team meetings and co-ordination of courses) • Sample of sessions observed (including facilitator behaviours) by the intervention developers • Qualitative interviews with participants, facilitators and intervention developers explored the style and content of delivery
Minimise contamination between conditions	• Providers trained in study design, including treatment and control conditions (with separate documentation when applicable), and associated procedures, to minimise contamination • Training supported by a written training manual and trial protocol and regular supervision of providers • Providers were monitored frequently on site and remotely • Facilitators and co-ordinators received separate manuals and the protocol

TABLE 6 Strategies within the STEPWISE programme that were intended to ensure fidelity (*continued*)

Goal	STEPWISE fidelity strategies
Receipt	
Ensure participant comprehension	• Facilitators asked participants questions, discussed materials, used scripts to help to summarise content; encouraged the use of activity logs; and structured content around achievement-based objectives • Qualitative interviews (sample) explored the experience and purpose of the programme
Ensure participant ability to use cognitive skills	• Facilitators encourage participants to consider strategies for overcoming obstacles to changing their behaviours • Session-specific (forms) and overall (qualitative interview) feedback
Ensure participant ability to perform behavioural skills	• Programme encourages self-monitoring, self-reporting of success and adherence • Programme encourages good practice to help overcome barriers (e.g. use of food diaries and 'triggers' for making less-healthy choices, mindfulness) and obstacles within sessions • Facilitators provided follow-up telephone contacts
Enactment	
Ensure participant use of cognitive skills	• Facilitators checked progress (and provided an opportunity to discuss the ongoing use of skills) during 1 : 1 interactions • Printed materials with space to record group exercises or tasks and goals were provided for use in, and between, sessions and after the course • Qualitative interviews explored the achievement of goals (self-report)
Ensure participant use of behavioural skills	• Frequency/duration of sessions and adherence monitored • Programme maintained longitudinally (booster and telephone support) • Qualitative interviews explored the use of skills that participants learned and their use or not (self-report)

Health economic methods

Introduction

The economic evaluation of the STEPWISE trial was conducted using both health and social care and societal perspectives. Individual participant data were used in the analysis to generate results for the cost-effectiveness of the intervention regarding its impact on cost-relative quality-adjusted life-years (QALYs), derived from the EQ-5D-5L and the SF-36 questionnaires, and weight change. The time horizon of the trial (3- and 12-month follow-up) was the same in the economic evaluation. The economic analyses included all trial participants. The comparison was between the group receiving the STEPWISE intervention and the group receiving a leaflet with advice. This analysis determined cost-effectiveness using the £20,000-per-QALY-gained threshold set by NICE. A sensitivity analysis was used to establish the effect of changes in costs and QoL measurement (comparing results using utility values from the EQ-5D and the SF-36)[51,98] on the results. Value sets for health-related QoL measures related to value sets containing preferences from a population in England for the EQ-5D-5L[51] and in the UK for the SF-36.[98]

Health and social care costs

Health and social care resources were calculated using the unit costs from the Personal Social Services Research Unit (PSSRU)[99] and NHS reference costs,[100] with service use data. Responses to the Client Service Receipt Inventory (CSRI)[101] questionnaire, which captured health and social care as well as other resource use, were collected for the 3 months before the baseline assessment and the 3-month follow-up and the 9 months before the 12-month follow-up. The CSRI includes information on hospital care (inpatient and outpatient), social care, primary care and criminal justice service contacts. Less frequently used health-care professional contacts were reported in the 'other health-care professional' category, including drug advisors, outreach workers, early intervention services, occupational therapists, drug service facilities and communities, using the CSRI. Medication prices from the *British National Formulary*[102] in March 2017 were

applied to the data on medication use by the participants in the study. All drugs for physical and mental health conditions, including those that could be bought over the counter, were included. Ongoing medications recorded on the CRF were used as a source of medication data.

Intervention costs

The intervention comprised four foundation sessions (2.5 hours each), three booster sessions (at 4, 7 and 10 months, of 2.5 hours each) and support contacts (telephone calls, texts and postcards) every 2 weeks. The base case was conducted to represent the scenario in which only four patients attended each session. This was to reflect lower attendance than the seven full sessions for the intervention. The cost of the accelerometer was omitted.

The foundation and booster sessions of the intervention were costed as group therapy sessions, using the mental health nurse wage level and related oncosts, combined with capital costs and other costs of the service at 2015–16 prices. The intervention unit costs, using the wages of a mental health nurse and a dietitian, were costed for a 2.5-hour session of the intervention. For most analyses, the results are reported for two mental health nurses facilitating a group session with six participants. The unit costs per person, calculated using the costs of a mental health nurse, were £88 for a group of four, £59 for a group of six and £44 for a group of eight (the costs for groups of six and eight were used in the sensitivity analyses). Support contacts by telephone were costed at the price of one nurse or dietitian per minute, multiplied by the length of the call. Text messages and postcards were costed at a nominal value of £5. The costs of the intervention were split between time periods, as the intervention booster sessions and support contacts continued after the 3-month period.

Societal costs

Average wage rates were applied to productivity losses and informal care time, which were obtained using data from the Office for National Statistics.[103] In the sensitivity analyses, we used minimum wage rates,[104] which were also applied to productivity losses and informal care, and the unit costs for a home-care worker for informal care using the figure from the PSSRU.[99]

Police officer contact time was calculated from police salary scales[105] and workforce statistics.[106] A cost of police contacts was included, but no other criminal justice system costs were included. The cost of a lost education day was calculated as the cost of a working day; as it was assumed that as the participants were all adults, this was more appropriate. The CSRI also recorded time lost from work, education and informal care from friends and family.

No discount rate was applied to the costs and QoL measures, as the follow-up period for participants was 1 year.

Health-related quality of life

Health-related QoL was measured using the EQ-5D-5L[107] and the SF-36/Short Form questionnaire-6 Dimensions (SF-6D).[98] The EQ-5D is the measure more commonly used in health technology assessments in England and is recommended by NICE. However, the EQ-5D is known to have a ceiling effect in schizophrenia, which is why the SF-6D was also used, as this measure is more likely to be normally distributed. The SF-36 questionnaire responses were converted to the SF-6D QoL measure for the analysis, using domain weightings from Brazier and Roberts.[108] QALYs were calculated from the tariff scores using the area under the curve method for both the EQ-5D-5L and the SF-6D QoL measures. It was assumed that there was a linear change between any two time points.

Statistical analyses

The net benefit approach was used in a cost–utility analysis of costs and both types of QALY data, and in a cost-effectiveness analysis with health/social care and societal costs. The net benefit is derived from the multiplication of a threshold value for a unit of outcome minus the cost.

Service use and cost differences between the two groups were described. The analysis of costs and outcomes was carried out in four combinations: (1) EQ-5D-5L QALY and health and social care costs; (2) EQ-5D-5L QALY and societal costs; (3) SF-6D QALY and health and social care costs; and (4) SF-6D QALY and societal costs.

Incremental cost-effectiveness ratios (ICERs) were computed by dividing incremental costs by incremental outcomes. Cost-effectiveness planes were constructed by obtaining, through bootstrapped regression models, 1000 pairs of cost and outcome differences and showing these on scatterplots. The proportion of replications in each quadrant could then be obtained.

Cost-effectiveness acceptability curves

Cost-effectiveness acceptability curves (CEACs) show the probability that one group is more cost-effective than the other for a chosen value of willingness to pay per unit of outcome. The STEPWISE economic evaluation uses the net benefit approach[109] with the 12-month follow-up results for these CEACs. The willingness-to-pay value that is used is the £20,000 NICE threshold for total health and social care costs. CEACs are also produced for societal costs at the 12-month follow-up; however, the relevant analysis for NICE methodology is from the health and social care perspective. The value of the willingness-to-pay threshold was also varied in values of £10,000 between £0 and £200,000, to show how the probability of cost-effectiveness changes as the threshold rises.

Missing data

The multiple imputation (chained equations) method[110] was applied to impute missing values for cost and QoL data, assuming that data were MAR before bootstrapping to carry out the cost-effectiveness analysis.

Sensitivity analysis

Three types of sensitivity analysis will be reported in the final analysis, with varying costs. First, costs of the intervention were used [mental health nurse (£1.18 per minute, £59 per session – two facilitators with a group of four patients)]. Second, informal care costs were calculated using two alternative unit costs: home care worker (£20 per weekday hour of a home care worker based on independent and social services home care) and minimum wage rate (£7.20 per hour in 2016). Third, productivity losses (lost employment time), valued using the average wage rate in the base case, are also calculated using the minimum wage rate[104] (£7.20 per hour in 2016). Each of these sensitivity analyses were carried out using values from both the EQ-5D and the SF-6D. No adjustments were made to take into account deaths during the study, as the numbers were so low.

Chapter 4 Results of the trial

Recruitment and participant flow

The first participant consented to the trial on 10 March 2015 and was randomised on 14 March 2015. The trial closed as scheduled on 31 March 2017, when the last 12-month follow-up was completed (*Figure 6*).

A total of 414 participants were randomised, of whom two were not included in any analyses: one was erroneously randomised, having previously withdrawn consent to randomisation, and a second withdrew all consent to use their data. Therefore, 412 participants (207 intervention, 205 control) were included in the following summaries.

Figure 7 shows that completion was slightly higher in the control group. There were three deaths, all in the intervention arm, owing to pulmonary embolism ($n = 1$), myocardial infarction ($n = 1$) and diabetic ketoacidosis in a person with type 2 diabetes mellitus previously treated with oral antidiabetes agents, leading to cardiac arrest ($n = 1$).

Intervention arm participants were categorised as non-attenders, attending one or two foundation ('core') sessions, attending three or four core sessions without any boosters or attending three or four core sessions with at least one booster. A total of 47 participants (22.7%) attended all core and booster sessions (*Table 7*). The mean number of sessions attended was 2.7 foundation sessions and 1.4 booster sessions (*Table 8*). The mean intervention group size as randomised was 6.3, but the mean number of participants who actually attended ranged from 4.0 to 4.4 during the foundation course and dropped to 2.7 to 3.0 during the booster sessions (see *Table 9*).
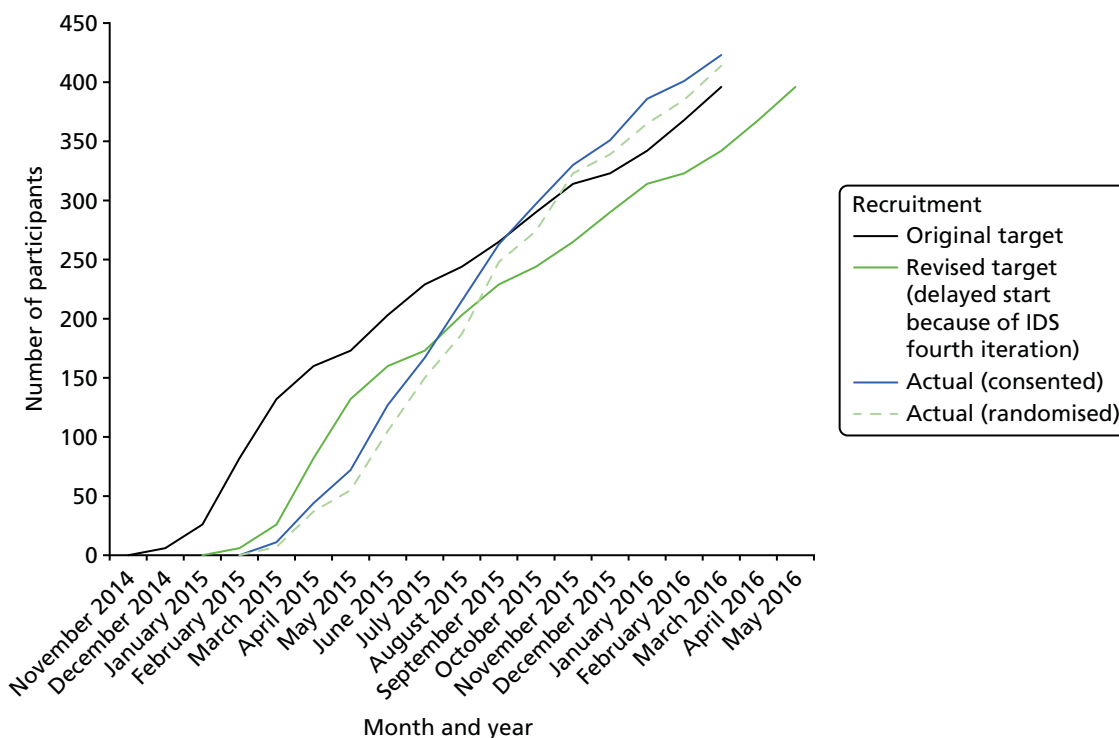
FIGURE 6 Randomisation by month. IDS, Intervention Development Study.
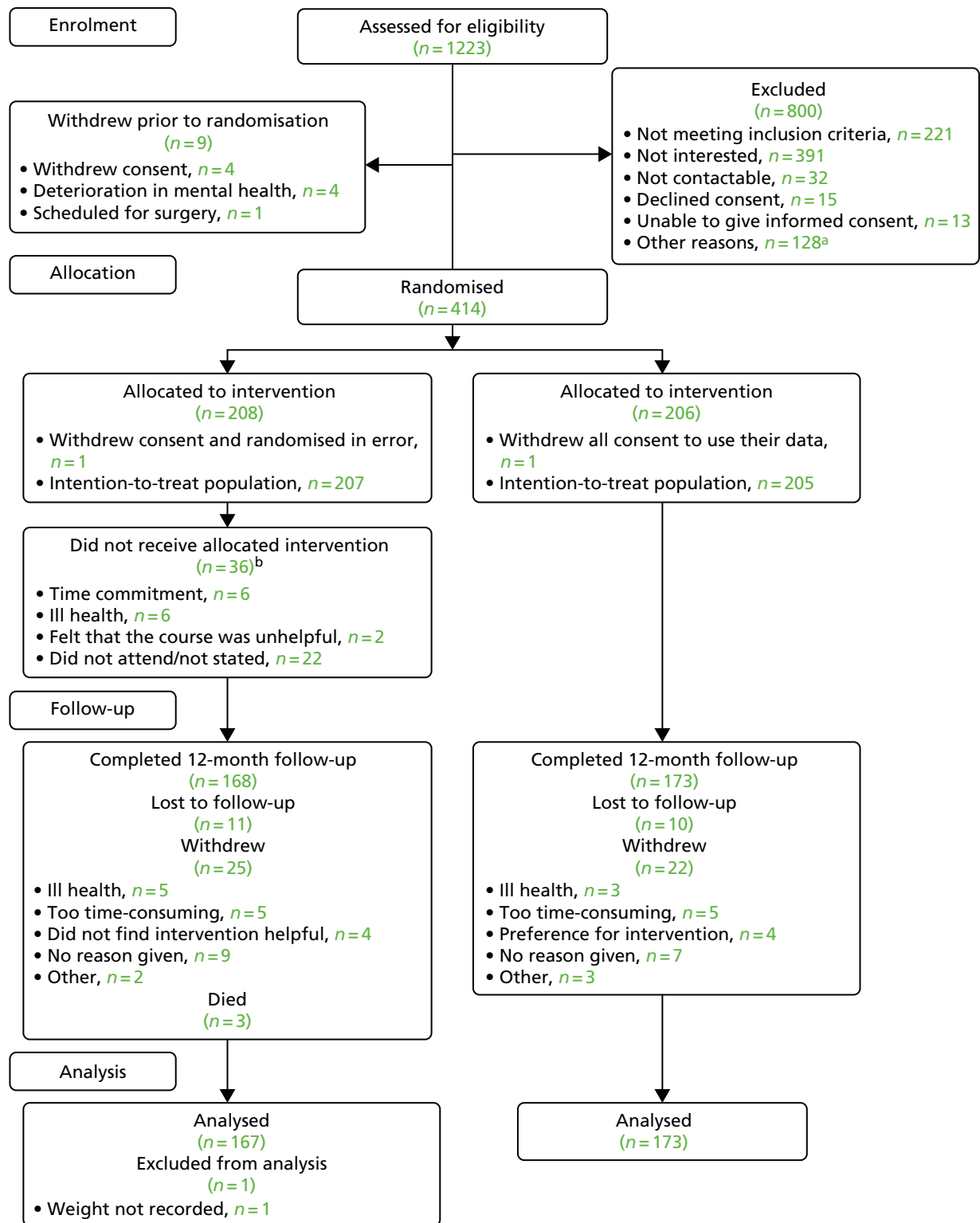
FIGURE 7 Consolidated Standards of Reporting Trials flow diagram. a, Referred but not contacted before end of recruitment ($n = 27$), current inpatient ($n = 18$), work ($n = 9$), Intervention Development Study participant ($n = 9$), discharged from CMHT ($n = 8$), too busy/away a lot ($n = 7$), not able to travel/out of area ($n = 5$), did not attend consent/baseline visit ($n = 5$), mental health problem relating to weight ($n = 5$), unknown ($n = 4$), other (specified reasons) ($n = 31$). b, Receipt of intervention defined as attending at least one foundation. Reproduced from Holt et al.[23] This is an Open Access article distributed in accordance with the terms of the Creative Commons Attribution (CC BY 4.0) license, which permits others to distribute, remix, adapt and build upon this work, for commercial use, provided the original work is properly cited. See: http://creativecommons.org/licenses/by/4.0/. The figure includes minor additions and formatting changes to the original text.

TABLE 7 Uptake of intervention

Attendance	n (%)
Non-attender	36 (17.4)
One or two core sessions	34 (16.4)
≥ 3 core and 0 booster sessions	26 (12.6)
≥ 3 core and ≥ 1 booster sessions	111 (53.6)
Attended all courses	47 (22.7)

TABLE 8 Attendance and average group size

Attendance and group size	Group size			
	Mean	Median	Minimum	Maximum
Group size at randomisation	6.3	6	3	11
Foundation courses[a]				
Week 1	4.4	4	2	9
Week 2	4.2	4	1	8
Week 3	4.2	4	2	9
Week 4	4.0	4	1	9
Booster sessions[a]				
Month 4	3.0	3	0	8
Month 7	2.8	3	0	7
Month 10	2.7	3	0	6

a Average number attending per course (at least 60 minutes).
Note
Reproduced from Holt *et al.*[23] This is an Open Access article distributed in accordance with the terms of the Creative Commons Attribution (CC BY 4.0) license, which permits others to distribute, remix, adapt and build upon this work, for commercial use, provided the original work is properly cited. See: http://creativecommons.org/licenses/by/4.0/. The table includes minor additions and formatting changes to the original text.

Overall, there were 3218 support contacts made with participants outside the group sessions, of which three-quarters were made by telephone. A total of 169 participants (81.6%) had one or more support contact; 167 participants (81%) had at least one telephone contact, among whom the average number of received telephone calls was 15, and 105 (50.7%) had at least one mail contact, with the average number being five. Face-to-face contact was less common, but 68 participants (32.9%) attended at least one session, with the average number of contacts being three and the average duration of these being just under 1 hour.

Table 9 compares support contact (i.e. contact other than group sessions) at the recruiting sites. Manchester made the most contacts overall, with the vast majority being by telephone (93.8%), with only one contact being face to face. Cornwall made the smallest percentage of contacts by telephone (41.1%), but had the largest percentage of contacts by mail and electronically. Leeds and York and Somerset had the largest percentages of face-to-face contacts – 11.5% and 12.6%, respectively, almost three times the sites' average of 4.4%.

TABLE 9 Number of contacts outside group sessions by site, overall and by contact type

| Site | Contact type, *n* (%) | | | | All contacts |
	Electronic	Face to face	Mail	Telephone	
Overall	88 (2.7)	141 (4.4)	555 (17.3)	2434 (75.6)	3218
Bradford	5 (2.5)	7 (3.5)	2 (1.0)	189 (93.1)	203
Cornwall	63 (15.2)	22 (5.3)	159 (38.4)	170 (41.1)	414
Devon	11 (4.2)	10 (3.8)	49 (18.6)	193 (73.4)	263
Leeds and York	0	30 (11.5)	61 (23.3)	171 (65.3)	262
Manchester	0	1 (0.2)	38 (6.1)	588 (93.8)	627
Sheffield	0	1 (0.4)	43 (18.5)	189 (81.1)	233
Somerset	0	17 (12.6)	34 (25.2)	84 (62.2)	135
South London	3 (1.4)	20 (9.1)	0	196 (89.5)	219
Southern Health	5 (1.1)	14 (3.0)	126 (26.9)	324 (69.1)	469
Sussex	1 (0.3)	19 (4.8)	43 (10.9)	330 (84.0)	393
Mean contact time (minutes)	1.8	59.4	0.4	5.2	6.3

Baseline data

The characteristics of the randomised participants are given in *Tables 10* and *11*. The groups were largely well balanced, but the intervention arm participants were, on average, 3 kg heavier at baseline, which is partially explained by the higher proportion of men in the intervention arm (55.6% vs. 46.3%; the average weight among men was 109 kg vs. 98 kg among women). The prevalence of type 2 diabetes mellitus was higher in the intervention arm (16.4% vs. 11.7%), whereas the control group included a larger proportion of participants with current depression (30.2% vs. 26.1%) and previous depression (28.3% vs. 24.2%).

TABLE 10 Baseline characteristics

| Characteristic | Trial arm | |
	Intervention (*N* = 207)	Control (*N* = 205)
Site, n (%)		
Bradford	17 (8.2)	19 (9.3)
Cornwall	21 (10.1)	21 (10.2)
Devon	21 (10.1)	21 (10.2)
Leeds and York	22 (10.6)	20 (9.8)
Manchester	31 (15.0)	29 (14.1)
Sheffield	18 (8.7)	17 (8.3)
Somerset	12 (5.8)	14 (6.8)
South London	16 (7.7)	14 (6.8)
Southern Health	27 (13.0)	27 (13.2)
Sussex	22 (10.6)	23 (11.2)
Age (years)		
Number of participants	207	205
Mean (SD)	40.0 (11.3)	40.1 (11.5)

TABLE 10 Baseline characteristics (*continued*)

Characteristic	Trial arm	
	Intervention (*N* = 207)	Control (*N* = 205)
Sex, n (%)		
Male	115 (55.6)	95 (46.3)
Female	92 (44.4)	110 (53.7)
Ethnicity, n (%)		
White	179 (86.5)	170 (82.9)
Asian	9 (4.3)	7 (3.4)
Black	12 (5.8)	19 (9.3)
Mixed	4 (1.9)	7 (3.4)
Other	3 (1.4)	2 (1.0)
Smoking status, n (%)		
Ex-smoker	55 (26.6)	52 (25.4)
Never smoked	54 (26.1)	45 (22.0)
Current smoker	98 (47.3)	108 (52.7)
Light smoker	18 (8.7)	20 (9.8)
Moderate smoker	37 (17.9)	32 (15.6)
Heavy smoker	43 (20.8)	55 (26.8)
Missing	0	1 (0.5)
Weight (kg)		
n	206	204
Mean (SD)	105.2 (22.2)	102.1 (22.1)
Median (IQR)	104.2 (89.0–116.2)	99.3 (88.0–113.0)
BMI (kg/m²)		
n	206	204
Mean (SD)	36.1 (7.2)	35.3 (7.2)
Median (IQR)	35.1 (31.0–39.5)	34.2 (29.9–39.1)
Waist circumference (cm)		
n	205	204
Mean (SD)	117.8 (15.6)	116.1 (17.4)
Median (IQR)	118.0 (106.0–128.2)	116.8 (104.5–125.5)
Systolic blood pressure (mmHg)		
n	205	203
Mean (SD)	126.4 (15.9)	124.0 (16.8)
Median (IQR)	126.0 (116.0–135.0)	123.0 (112.0–134.0)
Diastolic blood pressure (mmHg)		
n	205	203
Mean (SD)	82.5 (11.0)	81.9 (12.5)
Median (IQR)	82.0 (74.0–89.0)	81.0 (74.0–90.0)

TABLE 10 Baseline characteristics (*continued*)

Characteristic	Trial arm	
	Intervention (*N* = 207)	Control (*N* = 205)
Pulse (b.p.m.)		
n	204	203
Mean (SD)	84.5 (13.9)	83.8 (13.6)
Median (IQR)	84.5 (75.0–95.0)	84.0 (75.0–93.0)
HbA_{1c} (mmol/mol)		
n	171	170
Mean (SD)	41.5 (13.3)	39.9 (10.9)
Median (IQR)	37.0 (35.0–42.0)	38.0 (35.0–41.0)
HbA_{1c} (%)		
Mean (SD)	5.9 (1.2)	5.8 (1.0)
Median (IQR)	5.5 (5.4–6.0)	5.6 (5.4–5.9)
HbA_{1c} category		
< 6% (42 mmol/mol)	133 (64.3%)	139 (67.8%)
6–6.5% (42–47 mmol/mol)	10 (4.8%)	17 (8.3%)
6.5–7.5% (48–57 mmol/mol)	9 (4.3%)	7 (3.4%)
7.5–8.5% (58–68 mmol/mol)	9 (4.3%)	2 (1.0%)
≥ 8.5% (69 mmol/mol)	10 (4.8%)	6 (2.9%)
Missing	36 (17.4%)	34 (16.6%)
Total cholesterol (mmol/l)		
n	175	179
Mean (SD)	5.0 (1.2)	5.1 (1.2)
Median (IQR)	4.9 (4.2–5.8)	4.9 (4.2–5.7)
HDL cholesterol (mmol/l)		
n	170	173
Mean (SD)	1.2 (0.5)	1.2 (0.4)
Median (IQR)	1.2 (1.0–1.4)	1.2 (1.0–1.3)
Non-HDL cholesterol (mmol/l)		
n	169	174
Mean (SD)	3.8 (1.3)	3.9 (1.4)
Median (IQR)	3.8 (2.9–4.6)	3.8 (2.9–4.6)
Triglycerides (mmol/l)		
n	172	172
Mean (SD)	2.5 (2.0)	2.2 (1.7)
Median (IQR)	1.9 (1.4–2.8)	1.7 (1.2–2.8)
Fasting glucose (mmol/l)		
n	170	172
Mean (SD)	5.9 (2.2)	5.8 (2.3)
Median (IQR)	5.2 (4.8–6.1)	5.3 (4.7–6.0)

TABLE 10 Baseline characteristics (*continued*)

	Trial arm	
Characteristic	**Intervention (*N* = 207)**	**Control (*N* = 205)**
eGFR (ml/minute/1.73 m²), n (%)		
≤ 60	2 (1.0)	3 (1.5)
60–90	58 (28.0)	55 (26.8)
> 90	15 (7.2)	9 (4.4)
Missing	132 (63.8)	138 (67.3)
Evidence of hepatic disease?, n (%)		
No	167 (80.7)	167 (81.5)
Yes	5 (2.4)	7 (3.4)
Missing	35 (16.9)	31 (15.1)

b.p.m., beats per minute; eGFR, estimated glomerular filtration rate; HDL, high-density lipoprotein; IQR, interquartile range.

TABLE 11 Medical history

	Trial arm	
Diagnosis	**Intervention (*N* = 207)**	**Control (*N* = 205)**
Schizophrenia diagnosis type, n (%)		
ICD-10: F20	145 (70.0)	138 (67.3)
ICD-10: F25	30 (14.5)	36 (17.6)
First episode psychosis	32 (15.5)	31 (15.1)
OPCRIT+ diagnosis, n (%)		
Schizophrenia [F20]	37 (17.9)	37 (18.0)
Schizoaffective disorder [F25.X]	8 (3.9)	7 (3.4)
Other non-organic psychosis [F28.X]	72 (34.8)	69 (33.7)
Affective disorder [F3X.X, F30X, F31, F32]	11 (5.3)	14 (6.8)
Other	60 (29.0)	62 (30.2)
Not met	12 (5.8)	12 (5.9)
Missing	7 (3.4)	4 (2.0)
Diabetes mellitus status, n (%)		
Type 1	1 (0.5)	1 (0.5)
Type 2	34 (16.4)	24 (11.7)
Diagnosed chronic kidney disease, n (%)		
Current	0 (0.0)	1 (0.5)
Atrial fibrillation, n (%)		
Current	0 (0.0)	0 (0.0)
Past	2 (1.0)	1 (0.5)
Hypertension, n (%)		
Current	21 (10.1)	17 (8.3)

TABLE 11 Medical history (*continued*)

Diagnosis	Trial arm	
	Intervention (*N* = 207)	Control (*N* = 205)
Rheumatoid arthritis, n (%)		
Current	9 (4.3)	5 (2.4)
Heart attack, n (%)		
Past	0 (0.0)	3 (1.5)
Angina, n (%)		
Ongoing	1 (0.5)	5 (2.4)
Past	2 (1.0)	1 (0.5)
Stroke or TIA, n (%)		
Past	4 (1.9)	3 (1.5)
Peripheral vascular disease, n (%)		
Ongoing	0 (0.0)	1 (0.5)
Past	0 (0.0)	0 (0.0)
Depression, n (%)		
Current	54 (26.1)	62 (30.2)
Past	50 (24.2)	58 (28.3)
Any other relevant medical conditions, n (%)		
Yes	72 (34.8)	70 (34.1)
Has a first-degree relative who has had angina or a heart attack before the age of 60 years, n (%)		
No	170 (82.1)	158 (77.1)
Yes	36 (17.4)	44 (21.5)
Unknown	1 (0.5)	2 (1.0)
Has a first-degree relative with diabetes mellitus, n (%)		
No	158 (76.3)	146 (71.2)
Yes	47 (22.7)	56 (27.3)
Unknown	2 (1.0)	2 (1.0)
Has a history of heavy drinking or an alcohol problem,[a] n (%)		
No	157 (75.8)	153 (74.6)
Yes	50 (24.2)	52 (25.4)
Time since first contact with psychiatric services (years)		
Median (IQR)	14 (6–22)	15 (6–22)
Time since first contact with psychiatric services (years), n (%)		
< 1	7 (3.4)	9 (4.4)
1–2	8 (3.9)	16 (7.8)
2–5	29 (14.0)	20 (9.8)
5–10	27 (13.0)	27 (13.2)
10–20	66 (31.9)	65 (31.7)
≥ 20	70 (33.8)	68 (33.2)

TABLE 11 Medical history (*continued*)

Diagnosis	Trial arm	
	Intervention (*N* = 207)	Control (*N* = 205)
Years since started antipsychotics		
Median (IQR)	13 (5–20)	12 (5–20)
Time since started antipsychotic medication (years), n (%)		
< 1	12 (5.8)	12 (5.9)
1–2	11 (5.3)	20 (9.8)
2–5	28 (13.5)	19 (9.3)
5–10	28 (13.5)	33 (16.1)
10–20	71 (34.3)	69 (33.7)
≥ 20	57 (27.5)	52 (25.4)
Time since first symptoms of psychosis (years)		
Median (IQR)	15 (7–22)	15 (6–23)
Time since first symptoms of psychosis (years), n (%)		
< 1	8 (3.9)	9 (4.4)
1–2	5 (2.4)	11 (5.4)
2–5	26 (12.6)	20 (9.8)
5–10	27 (13.0)	26 (12.7)
10–20	70 (33.8)	70 (34.1)
≥ 20	66 (31.9)	69 (33.7)
Not recorded	5 (2.4)	0 (0.0)

IQR, interquartile range; TIA, transient ischaemic attack.
a   Based on the opinion of the site PI.

Medication use on entry is given in *Table 12*. All bar one participant were recorded as being currently prescribed antipsychotic medication and over half reported use of antidepressant medication, all of which factors were reasonably well balanced between the groups.

Course delivery and protocol non-compliance

Although the courses were designed to be delivered by two trained facilitators, 16 of the 231 courses (eight foundation and eight booster) were led by a single facilitator owing to staff unavailability. At one centre, the wave 2 7-month booster session (with five participants allocated to the group) did not take place owing to lack of facilitator availability. At another centre, two booster sessions were delivered by the external (fully trained NHS employee) fidelity assessor who delivered the session on the day because neither facilitator was available owing to sickness. In addition, the support contacts were not always at the intended intervals of approximately every 2 weeks; 8% of contacts occurred within 1 week of the previous contact and 10% occurred more than 3 weeks after the previous contact.

Of the 54 individuals who facilitated at least one course, 47 completed a short survey describing their qualifications and experience before delivering the intervention. Twenty-two were mental health nurses (47%), six were support workers (13%), five were occupational therapists (11%) and the remainder were

TABLE 12 Medications at baseline

	Participants in each trial arm, _n_ (%)	
Psychiatric medication	Intervention (_N_ = 207)	Control (_N_ = 205)
Antipsychotic medication at baseline		
Any antipsychotic	207 (100.0)	204 (99.5)[a]
Haloperidol	7 (3.4)	3 (1.5)
Amisulpride	21 (10.1)	16 (7.8)
Aripiprazole	40 (19.3)	34 (16.6)
Clozapine	89 (43.0)	81 (39.5)
Olanzapine	31 (15.0)	31 (15.1)
Quetiapine	28 (13.5)	24 (11.7)
Risperidone	10 (4.8)	21 (10.2)
Flupentixol	8 (3.9)	11 (5.4)
Zuclopenthixol	10 (4.8)	21 (10.2)
Paliperidone	7 (3.4)	8 (3.9)
Other antipsychotic	19 (9.2)	9 (4.4)
Antidepressant medication at baseline		
Any antidepressant	131 (63.3)	129 (62.9)
Citalopram	19 (9.2)	13 (6.3)
Lithium	8 (3.9)	9 (4.4)
Mirtazepine	9 (4.3)	10 (4.9)
Other antidepressant	107 (51.7)	115 (56.1)

a One participant had no antipsychotics listed at baseline either on the CRF or self-reported medications. This was most likely a data error rather than an ineligible participant.

from other disciplines. Thirty-three (70%) were trained to graduate or postgraduate level; with the remainder mostly having vocational qualifications (_n_ = 11, 23%). Facilitators had spent, on average, 13 years working in mental health (range 2–40 years); 13 facilitators reported a career of between 1 and 17 years (mean 6 years) working in physical health. Facilitators were asked to rate their confidence in group facilitation skills on a 5-point scale; the majority rated their abilities as '3' (_n_ = 16, 34%) or '4' (_n_ = 24, 51%), with six rating their confidence as '5' (very confident) and one scoring themselves as '2'.

Of the 230 foundation and booster courses delivered, 162 (71%) included a mental health nurse as a facilitator, 80 (35%) involved a support worker and 31 (13%) involved an occupational therapist. Eight of the 10 sites utilised facilitators with substantial experience of mental health (> 10 years' experience). By contrast, only two sites utilised facilitators with experience of physical health; the average experience (summed across all courses) was 10 years in Manchester, 7 years in London and < 2 years elsewhere.

Outcomes and estimation

Weight change (primary end point)

Among participants completing follow-up, the weight change was almost identical for the intervention and control arms. At 3 months, there was a reduction of 0.2 kg in the intervention arm and an increase of 0.4 kg in the control arm (difference = –0.55 kg, 95% CI –1.44 to 0.35 kg; _p_ = 0.230). At 12 months (the timing of

the primary comparison), the mean reduction in weight was 0.47 kg in the intervention group and 0.51 kg in the control group (difference = 0.04 kg, 95% CI −1.59 to 1.67 kg; p = 0.964). The distributions are shown in *Figure 8* and further summaries are presented in *Table 13*. There was considerable variation in the weight change in both groups, ranging from −24 kg to +30 kg in the intervention arm and from −25 kg to +30 kg in the control arm.

Figure 9 shows the mean and 95% CI for the adjusted mean weight change by time point and group. The means are adjusted for the primary covariates (recruiting site, years since starting antipsychotics, baseline weight and course identifier). The mean weight loss was similar between arms and was some distance from the 4.5 kg defined as the minimally clinically important difference in the sample size calculation.

The weight change by recruiting centre is displayed in *Figure 10*. The difference between the intervention and control arms ranged from −2.6 kg to +7.0 kg. Adding an interaction term between site and treatment to the primary model gave a test statistic of $\chi^2_{(9)} = 14.9$ (p = 0.094), indicating some evidence of a variation in the size of intervention effect between sites.

Other weight-related end points

The weight, BMI and waist circumference outcomes are also presented in *Table 13*. Although the proportion of participants reporting any weight reduction was slightly higher in the intervention arm, the magnitude of the difference was almost identical between the two trial arms. None of the comparisons reached statistical or clinical significance.
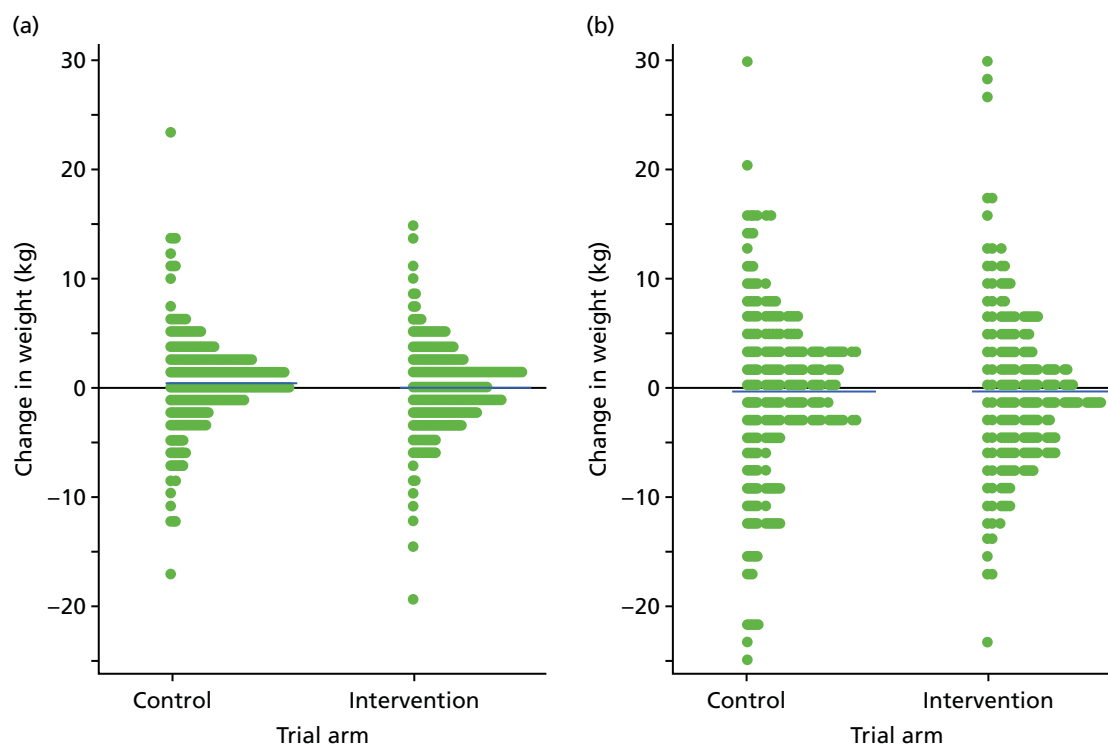
FIGURE 8 Weight change. (a) 3 months and (b) 12 months. Reproduced from Holt *et al*.[23] This is an Open Access article distributed in accordance with the terms of the Creative Commons Attribution (CC BY 4.0) license, which permits others to distribute, remix, adapt and build upon this work, for commercial use, provided the original work is properly cited. See: http://creativecommons.org/licenses/by/4.0/. The figure includes minor additions and formatting changes to the original.
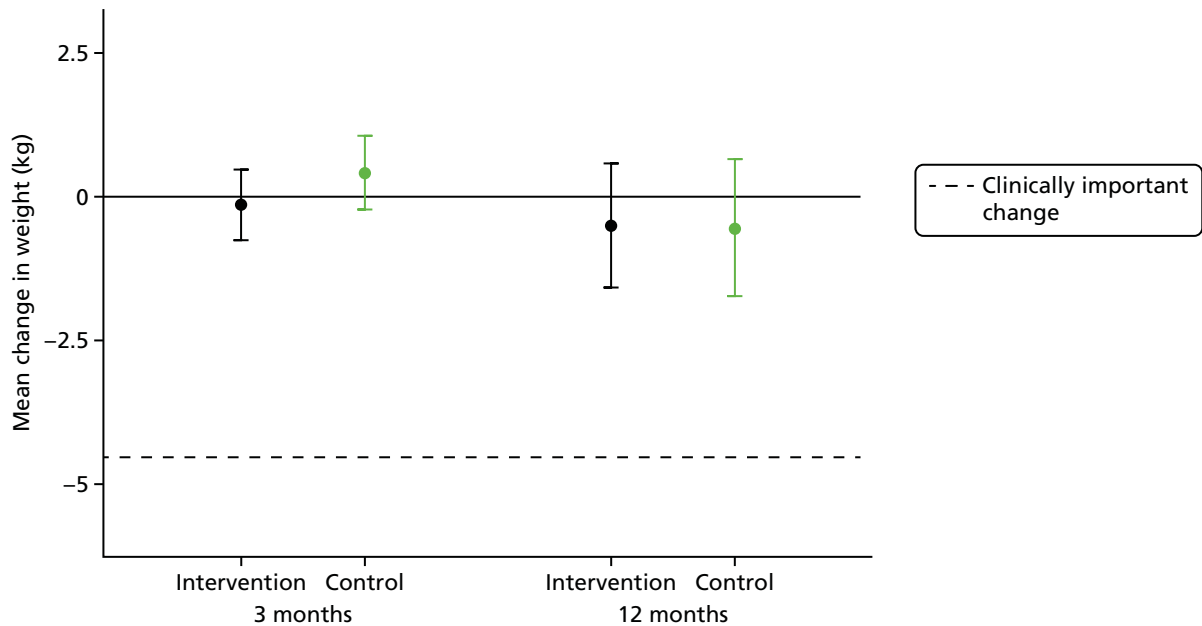
FIGURE 9 Mean and 95% CI for weight change.
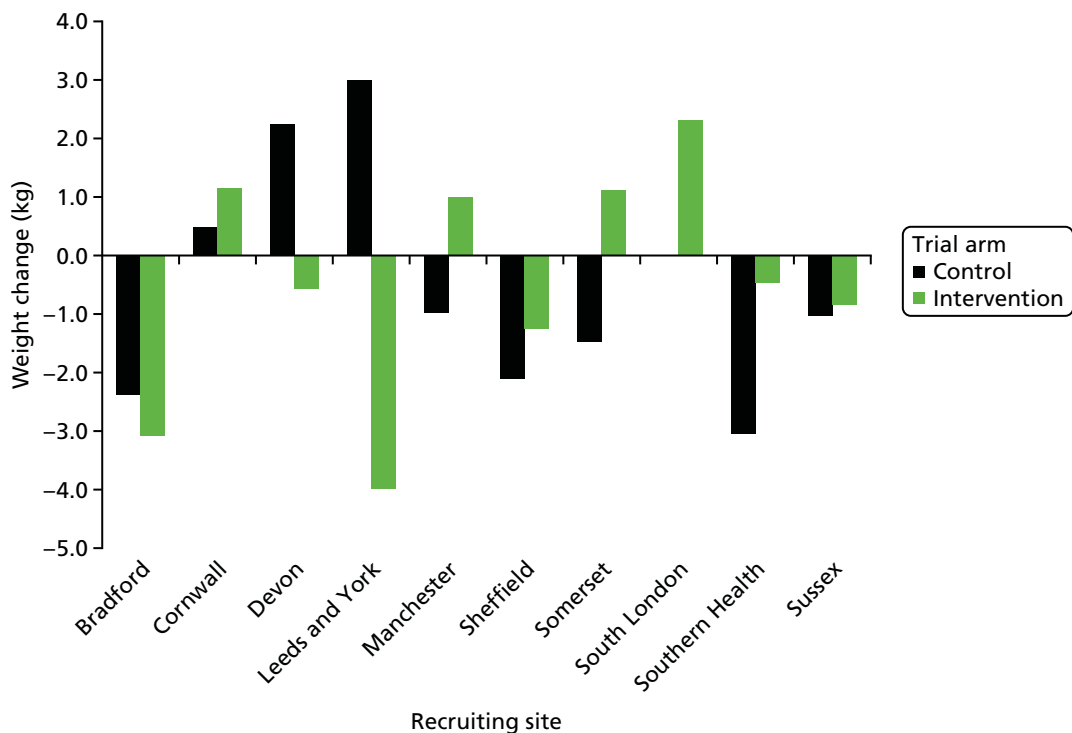
FIGURE 10 Mean weight change by recruiting site.

Sensitivity analyses of weight change

A number of sensitivity analyses were undertaken for weight change with regard to alternative model types, covariates and missing data assumptions (*Figure 11*). The weight change at 12 months was refitted with sex included as a covariate, as the groups were imbalanced in this; doing so made little difference, as sex was not associated with weight loss. The model assumptions were also reassessed using a mixed-effects model, by CACE (using the same covariates) to assess the impact of uptake, and with missing data assumed to be MAR using predictive mean matching imputation. In all cases, the difference between groups remained small.

TABLE 13 Weight change

Characteristic	Trial arm		Mean difference[a] (95% CI)	p-value
	Intervention (N = 207)	Control (N = 205)		
Weight (kg) Baseline				
n	206	204		
Mean (SD)	105.2 (22.2)	102.1 (22.1)		
3 months				
n	178	180		
Mean (SD)	104.7 (21.5)	103.1 (23.5)		
Change mean (SD)	–0.2 (4.4)	0.4 (4.7)	–0.55 (–1.44 to 0.35)	0.230
12 months				
n	167	173		
Mean (SD)	104.1 (21.1)	101.3 (23.7)		
Change mean (SD)	–0.5 (7.9)	–0.5 (8.3)	0.04 (–1.58 to 1.66)	0.963
Change in weight (%) 3 months				
n	178	180		
Mean (SD)	–0.0 (4.3)	0.4 (4.4)	–0.4 (–1.3 to 0.5)	0.350
12 months				
n	167	173		
Mean (SD)	–0.4 (7.9)	–0.5 (8.2)	0.0 (–1.6 to 1.7)	0.964
Maintained or lost weight				
3 months	93 (52.2%)	80 (44.2%)	1.35 (0.88 to 2.05)[b]	0.169
12 months	98 (58.3%)	88 (50.9%)	1.35 (0.85 to 2.14)[b]	0.206
BMI (kg/m²) Baseline				
n	206	204		
Mean (SD)	36.1 (7.2)	35.3 (7.2)		
3 months				
n	178	180		
Mean (SD)	35.8 (7.1)	35.5 (7.4)	–0.15 (–0.47 to 0.16)	0.337
12 months				
n	167	173		
Mean (SD)	35.6 (7.2)	34.8 (7.3)	0.05 (–0.51 to 0.60)	0.869

TABLE 13 Weight change (*continued*)

Characteristic	Trial arm		Mean difference[a] (95% CI)	*p*-value
	Intervention (*N* = 207)	Control (*N* = 205)		
Waist circumference (cm) Baseline				
n	205	204		
Mean (SD)	117.8 (15.6)	116.1 (17.4)		
3 months				
n	178	180		
Mean (SD)	116.8 (15.2)	115.4 (17.0)	0.79 (–0.65 to 2.22)	0.284
12 months				
n	164	170		
Mean (SD)	116.4 (16.1)	114.0 (17.7)	1.23 (–0.74 to 3.20)	0.222

a Mean difference derived from GEEs model in which the covariates were treatment group, time since started antipsychotic medication and baseline measure.
b Odds ratio derived from GEEs model in which the covariates were the treatment group, time since started antipsychotic medication and baseline weight.
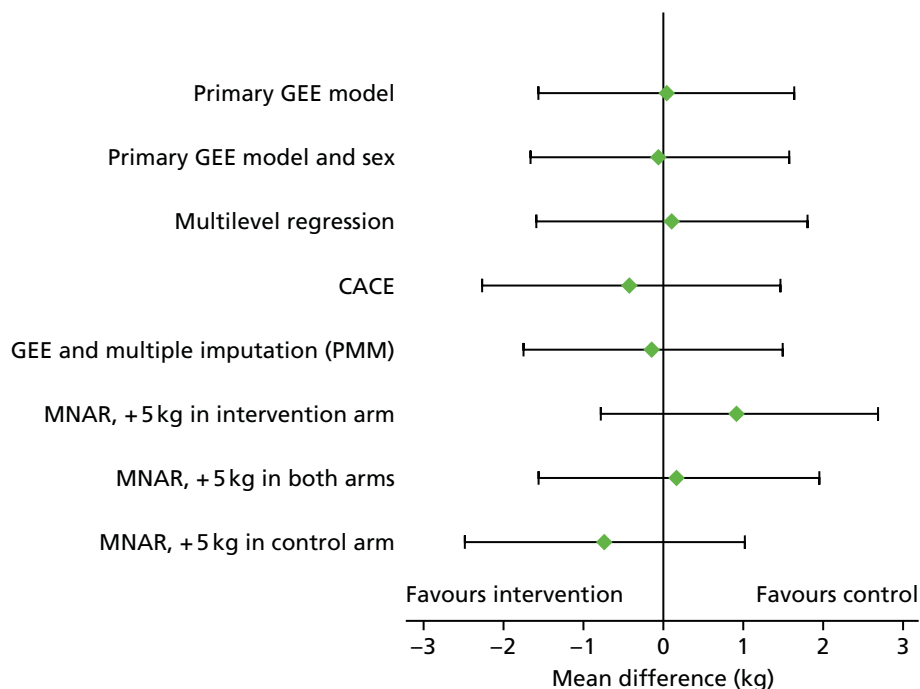
FIGURE 11 Sensitivity analyses for weight change. PMM, predictive mean matching.

It is possible that some participants did not remain in the study because of their weight (i.e. informative dropout or MNAR), and the above models do not account for this. As a final sensitivity analysis, missing weight was imputed in which those who withdrew were assigned weights up to 5 kg more than their predicted value; this was done in the intervention arm only, the control arm only and both. Although this affected the estimated treatment differences, the differences remained small and were not statistically significant.

The impact of the intervention by subgroup was estimated in four subgroups, as described in *Chapter 3*, *Analysis of other outcomes*. In all cases, the difference between groups was small and not of clinical or statistical significance (*Figure 12*).

Predictors of weight change

A series of linear regressions were undertaken to assess whether or not any participant characteristics were associated with weight change. The univariate analyses are presented in *Table 14*. Few of the characteristics appeared to systematically explain weight gain or loss. Weight loss was modestly associated with age, with weight reduction increasing by 0.8 kg per 10 additional years (95% CI 0.0 to 1.5 kg; $p = 0.042$), participants with a diagnosis of schizoaffective disorder had a greater mean weight loss (2.7 kg) than those with first episode psychosis (0.3 kg) or schizophrenia (0.01 kg gain; global test, $p = 0.075$). Weight loss was greater among female participants and was, on average, greater among those with higher baseline weight and longer duration on antipsychotics, but none of these findings was statistically significant. Additional analyses based on non-linear associations, using fractional polynomial regression and multivariable regression models, did not reveal any important predictors of weight change. There was no association between total (group, telephone and face-to-face) contact time and weight change (see *Figure 13*).

Participants who were prescribed lithium had a statistically significantly greater weight reduction than those who were not (mean difference = 4.4 kg, 95% CI 0.4 to 8.5 kg; $p = 0.033$), although this accounted for only 16 participants completing the trial. Among participants taking antipsychotics, weight loss was greatest among participants on paliperidone ($n = 12$, average weight loss 3.4 kg) and lowest among those on aripiprazole ($n = 63$, 1.2-kg gain) and other antipsychotics ($n = 20$, 1.6 kg gain). Participants who changed medication within 3 months of randomisation had a higher average weight gain than those who did not (antipsychotic change: $n = 29$, mean difference = 3.4 kg, 95% CI 0.3 to 6.5 kg; $p = 0.031$; antidepressant
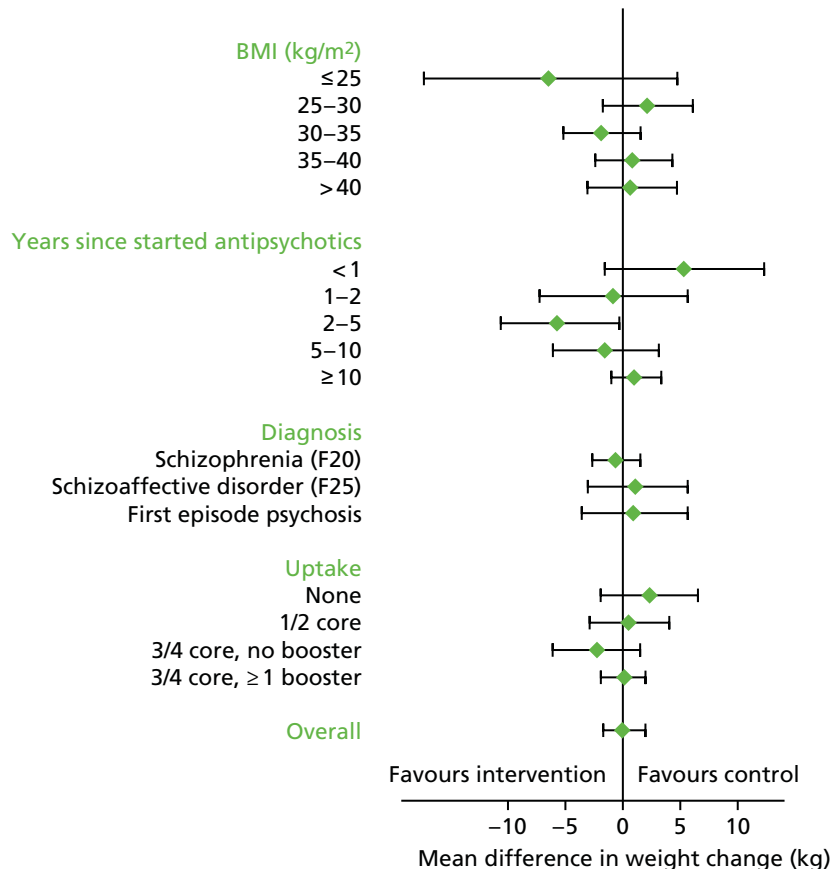
FIGURE 12 Weight change by subgroup.

TABLE 14 Predictors of weight loss at 12 months

Predictor	Mean difference (95% CI)	*p*-value
Baseline demographics		
Age (per 10-year increase)	–0.8 (–1.5 to –0.0)	0.042
Sex (female vs. male)	–1.2 (–2.9 to 0.6)	0.182
Weight at baseline (per 10 kg)	–0.1 (–0.5 to 0.3)	0.587
Disease characteristics and comorbidities *Diagnosis*		
Schizoaffective disorder vs. schizophrenia	–2.7 (–5.1 to –0.4)	0.023
First episode psychosis vs. schizophrenia	–0.4 (–2.8 to 2.1)	0.774
Time since started antipsychotics (per 10 years)	–0.5 (–1.3 to 0.4)	0.253
Presence of diabetes mellitus	–2.1 (–4.6 to 0.5)	0.109
Evidence of hepatic disease	–1.5 (–6.2 to 3.2)	0.532
Mental health at baseline		
Diagnosis of clinical depression	0.7 (–0.3 to 1.7)	0.194
BPRS	0.0 (–0.1 to 0.1)	0.845
B-IPQ overall total score	–0.4 (–0.9 to 0.1)	0.134
PHQ-9 score	–0.0 (–0.2 to 0.1)	0.525
SF-36 QoL at baseline		
Physical functioning	0.0 (–0.0 to 0.1)	0.106
Role limitations owing to physical health	0.0 (–0.0 to 0.0)	0.746
Role limitations owing to emotional problems	–0.0 (–0.0 to 0.0)	0.529
Energy/fatigue score	–0.0 (–0.1 to 0.0)	0.469
Emotional well-being	–0.0 (–0.1 to 0.0)	0.380
Social functioning	0.0 (–0.0 to 0.0)	0.763
Bodily pain	0.0 (–0.0 to 0.0)	0.462
General health	–0.0 (–0.0 to 0.0)	0.876
Antipsychotic medication at baseline		
Amisulpride	–1.8 (–5.1 to 1.5)	0.274
Aripiprazole	2.1 (–0.1 to 4.3)	0.061
Clozapine	0.3 (–1.5 to 2.0)	0.757
Flupentixol	–2.1 (–6.0 to 1.7)	0.276
Haloperidol	–0.9 (–5.8 to 4.0)	0.725
Paliperidone	–3.1 (–7.7 to 1.6)	0.199
Olanzapine	–0.6 (–2.9 to 1.8)	0.642
Quetiapine	0.1 (–2.4 to 2.6)	0.941
Risperidone	–0.2 (–3.6 to 3.1)	0.893
Zuclopenthixol	–1.2 (–4.5 to 2.1)	0.471
Other antipsychotic	2.2 (–1.5 to 5.9)	0.237

TABLE 14 Predictors of weight loss at 12 months (*continued*)

Predictor	Mean difference (95% CI)	*p*-value
Antidepressant medication at baseline		
Any antidepressant	–0.2 (–2.0 to 1.6)	0.811
Citalopram	1.3 (–1.9 to 4.5)	0.415
Lithium	–4.4 (–8.5 to –0.4)	0.033
Mirtazepine	0.4 (–3.7 to 4.5)	0.851
Other antidepressant	–0.4 (–2.1 to 1.4)	0.666
Post-baseline medication and change in medication		
Changed antipsychotics by 3 months	3.4 (0.3 to 6.5)	0.031
Changed antipsychotics by 12 months	–0.2 (–2.6 to 2.2)	0.856
On antidepressants at 3 months	0.4 (–1.4 to 2.2)	0.660
Changed antidepressants by 3 months	6.1 (2.3 to 9.9)	0.002
On antidepressants at 12 months	0.0 (–1.8 to 1.8)	0.963
Changed antidepressants by 12 months	1.5 (–0.9 to 3.8)	0.220
Weight loss programme		
Attended any weight loss programme over 12 months	–0.1 (–2.8 to 2.7)	0.965
Intervention uptake		
Total contact time (hours)	–0.1 (–0.4 to 0.2)	0.607

change: *n* = 18, mean difference = 6.1 kg, 95% CI 2.3 to 9.9 kg; *p* = 0.002), but changes over the full 12 months were not associated with weight change.

Finally, there was no association between total contact time (summed across foundation sessions, booster sessions and support contact) and weight loss (*Figure 13*).
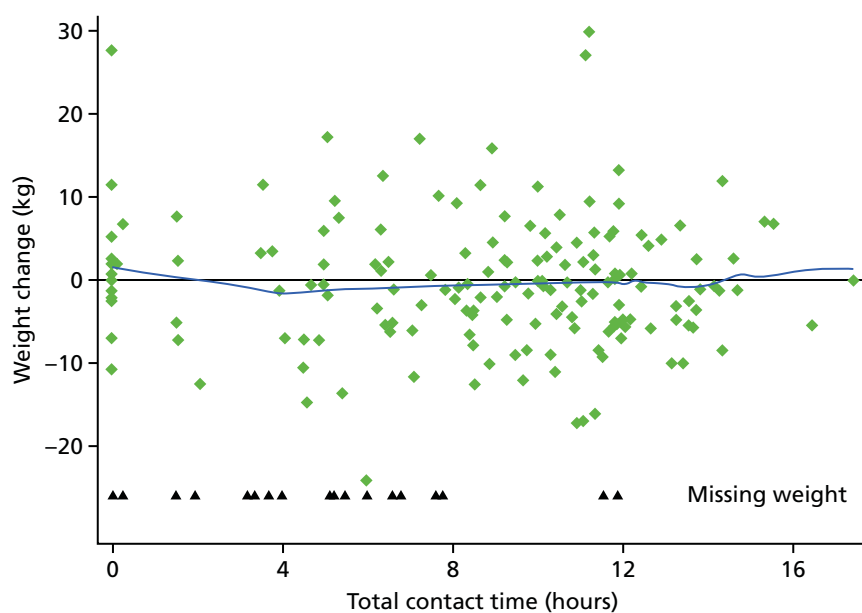
FIGURE 13 Weight loss at 12 months vs. total contact time (group session and support contact). The line is a locally weighted scatterplot smoother with bandwidth 0.4.

Other vital signs

The vital signs (blood pressure and pulse) at baseline, 3 months and 12 months are presented in *Table 15*. Systolic (but not diastolic) blood pressure was significantly higher in the intervention group at 3 months (difference = 2.4 mmHg, 95% CI 0.1 to 4.6 mmHg), but otherwise no change was apparent either between groups or across time points.

TABLE 15 Vital signs

Vital sign	Trial arm		Mean difference (95% CI)	*p*-value
	Intervention (*N* = 207)	Control (*N* = 205)		
Systolic blood pressure (mmHg) *Baseline*				
n	205	203		
Mean (SD)	126.4 (15.9)	124.0 (16.8)		
3 months				
n	178	179		
Mean (SD)	126.9 (16.2)	122.8 (15.7)	2.4 (0.1 to 4.6)	0.040
12 months				
n	164	168		
Mean (SD)	124.7 (15.2)	122.2 (16.4)	1.7 (–1.1 to 4.6)	0.237
Diastolic blood pressure (mmHg) *Baseline*				
n	205	203		
Mean (SD)	82.5 (11.0)	81.9 (12.5)		
3 months				
n	178	179		
Mean (SD)	82.2 (11.0)	81.4 (12.2)	0.4 (–1.5 to 2.3)	0.696
12 months				
n	164	168		
Mean (SD)	82.2 (10.3)	81.1 (10.5)	1.1 (–0.7 to 3.0)	0.231
Pulse (b.p.m.) *Baseline*				
n	204	203		
Mean (SD)	84.5 (13.9)	83.8 (13.6)		
3 months				
n	178	180		
Mean (SD)	86.1 (13.7)	83.6 (16.0)	2.1 (–0.5 to 4.6)	0.108
12 months				
n	164	168		
Mean (SD)	84.4 (13.9)	82.2 (14.0)	1.2 (–0.8 to 3.3)	0.245

b.p.m., beats per minute.

Laboratory measurements

The laboratory measurements at baseline and 12 months are presented in *Table 16*. No change was apparent either between groups or across time points.

TABLE 16 Laboratory measurements

Laboratory measurement	Trial arm		Mean difference (95% CI)	*p*-value
	Intervention (*N* = 207)	Control (*N* = 205)		
HbA₁c (mmol/mol) *Baseline*				
n	171	171		
Mean (SD)	41.5 (13.3)	39.9 (10.9)		
12 months				
n	134	132		
Mean (SD)	42.8 (15.4)	41.1 (14.1)		
Change from baseline				
n	119	118		
Mean (SD)	0.7 (7.9)	0.6 (5.6)	0.2 (–1.5 to 1.9)	0.807
HbA₁c (%) *Baseline*				
n	171	171		
Mean (SD)	5.9 (1.2)	5.8 (1.0)		
12 months				
n	134	132		
Mean (SD)	6.1 (1.4)	5.9 (1.3)		
Change from baseline				
n	119	118		
Mean (SD)	0.1 (0.7)	0.1 (0.5)		
Fasting glucose (mmol/l) *Baseline*				
n	170	172		
Mean (SD)	5.9 (2.2)	5.8 (2.3)		
12 months				
n	137	132		
Mean (SD)	6.4 (3.0)	6.0 (2.8)		
Change from baseline				
n	123	122		
Mean (SD)	0.3 (2.1)	0.1 (1.5)	0.3 (–0.2 to 0.8)	0.242
Total cholesterol (mmol/l) *Baseline*				
n	175	179		
Mean (SD)	5.0 (1.2)	5.1 (1.2)		

continued

TABLE 16 Laboratory measurements (*continued*)

Laboratory measurement	Trial arm		Mean difference (95% CI)	*p*-value
	Intervention (*N* = 207)	Control (*N* = 205)		
12 months				
n	143	138		
Mean (SD)	4.9 (1.2)	5.1 (1.1)		
Change from baseline				
n	129	127		
Mean (SD)	–0.2 (1.2)	–0.1 (0.9)	–0.2 (–0.4 to 0.1)	0.176
HDL cholesterol (mmol/l) *Baseline*				
n	170	173		
Mean (SD)	1.2 (0.5)	1.2 (0.4)		
12 months				
n	143	137		
Mean (SD)	1.2 (0.6)	1.2 (0.3)		
Change from baseline				
n	125	122		
Mean (SD)	0.0 (0.7)	–0.0 (0.3)	0.0 (–0.1 to 0.1)	0.824
Triglycerides (mmol/l) *Baseline*				
n	172	172		
Mean (SD)	2.5 (2.0)	2.2 (1.7)		
12 months				
n	139	135		
Mean (SD)	2.4 (1.4)	2.4 (2.2)		
Change from baseline				
n	124	120		
Mean (SD)	–0.2 (1.8)	0.2 (1.7)	–0.2 (–0.6 to 0.1)	0.203
Non-HDL cholesterol (mmol/l) *Baseline*				
n	169	174		
Mean (SD)	3.8 (1.3)	3.9 (1.4)		
12 months				
n	143	136		
Mean (SD)	3.7 (1.2)	3.8 (1.2)		
Change from baseline				
n	124	121		
Mean (SD)	–0.2 (1.4)	–0.2 (0.9)	–0.1 (–0.4 to 0.2)	0.428

HDL, high-density lipoprotein.

Accelerometry

Table 17 shows the results of the accelerometry. A total of 352 participants had baseline recordings for the primary accelerometry end point [(ENMO) i.e. average acceleration], of whom 302 had worn the GENEActiv for at least 4 days and therefore had a valid baseline measure. Of these, valid ENMO data were available in 222 participants at 3 months and in 209 participants at 12 months, meaning that the change in accelerometry could be estimated in 54% and 51% of the trial population at 3 and 12 months, respectively.

Overall baseline physical activity was low in both groups. Intervention arm participants were, on average, more active than control arm participants both before randomisation and after randomisation, but, after adjusting for baseline, few of the differences were statistically significant. The exception was MVPA, measured at weekends at the 3-month follow-up, which was modestly greater in the intervention group. The mean length of MVPA in the intervention and control groups was 70 versus 58 minutes per day (difference of 9.2 minutes per day, 95% CI 1.7 to 16.7 minutes per day; $p = 0.016$) for 5-minute bouts and 11 versus 7 minutes per day for 10-minute bouts (difference of 5.6 minutes per day, 95% CI 2.0 to 9.3 minutes per day; $p = 0.003$). The corresponding outcome for acceleration was not statistically significant (20 vs. 19 mg, difference = 1.0 mg, 95% CI –0.3 to 2.4 mg; $p = 0.140$). None of the remaining outcomes was different between the trial arms.

TABLE 17 Accelerometry (all data)

Measure of physical activity	Trial arm		Mean difference (95% CI)	*p*-value
	Intervention (*N* = 207)	Control (*N* = 205)		
Mean acceleration magnitude, m*g* (ENMO) *Baseline*				
n	160	152		
Mean (SD)	21.3 (7.9)	20.8 (7.3)		
3 months				
n	123	130		
Mean (SD)	21.7 (9.0)	19.8 (7.1)	–0.3 (–1.4 to 0.9)	0.654
12 months				
n	120	134		
Mean (SD)	22.4 (8.1)	20.5 (8.5)	0.1 (–1.5 to 1.6)	0.947
Mean acceleration magnitude (all days measured) *Baseline*				
n	160	152		
Mean (SD)	21.3 (7.9)	20.8 (7.4)		
3 months				
n	123	130		
Mean (SD)	21.7 (9.0)	19.8 (7.1)	–0.4 (–1.5 to 0.8)	0.555
12 months				
n	120	134		
Mean (SD)	22.4 (8.2)	20.5 (8.5)	0.2 (–1.4 to 1.7)	0.844

TABLE 17 Accelerometry (all data) (*continued*)

Measure of physical activity	Trial arm		Mean difference (95% CI)	*p*-value
	Intervention (*N* = 207)	Control (*N* = 205)		
Mean acceleration magnitude (weekends) *Baseline*				
n	167	154		
Mean (SD)	19.6 (8.0)	19.8 (8.3)		
3 months				
n	128	139		
Mean (SD)	20.4 (9.6)	18.7 (6.9)	1.0 (–0.3 to 2.4)	0.140
12 months				
n	126	137		
Mean (SD)	20.9 (8.6)	19.4 (8.8)	0.3 (–1.5 to 2.1)	0.708
Mean acceleration magnitude (weekdays) *Baseline*				
n	159	153		
Mean (SD)	22.1 (8.3)	21.1 (7.1)		
3 months				
n	125	129		
Mean (SD)	22.1 (9.2)	20.2 (7.5)	–0.7 (–2.0 to 0.6)	0.278
12 months				
n	124	136		
Mean (SD)	23.0 (8.5)	20.9 (8.6)	0.0 (–1.6 to 1.6)	0.994
MVPA, based on 5-second epochs (all days) *Baseline*				
n	160	152		
Mean (SD)	75.6 (45.9)	72.4 (42.2)		
3 months				
n	123	130		
Mean (SD)	77.5 (53.3)	64.1 (39.4)	–0.5 (–7.7 to 6.8)	0.902
12 months				
n	120	134		
Mean (SD)	79.8 (50.3)	68.9 (47.2)	0.4 (–8.6 to 9.3)	0.939
MVPA, 5-second bout duration (weekends) *Baseline*				
n	167	154		
Mean (SD)	65.7 (44.7)	67.5 (47.0)		
3 months				
n	128	139		
Mean (SD)	70.3 (55.1)	57.9 (37.5)	9.2 (1.7 to 16.7)	0.016
12 months				
n	126	137		
Mean (SD)	71.9 (50.0)	63.0 (48.3)	2.1 (–7.9 to 12.1)	0.677

TABLE 17 Accelerometry (all data) (*continued*)

Measure of physical activity	Trial arm		Mean difference (95% CI)	*p*-value
	Intervention (*N* = 207)	Control (*N* = 205)		
MVPA, based on 5-second epochs (weekdays) *Baseline*				
n	159	153		
Mean (SD)	21.6 (22.8)	17.6 (17.8)		
3 months				
n	125	129		
Mean (SD)	20.6 (25.8)	14.3 (17.7)	–2.3 (–10.0 to 5.5)	0.563
12 months				
n	124	136		
Mean (SD)	23.6 (28.7)	18.0 (23.3)	–0.4 (–9.7 to 8.8)	0.926
MVPA, > 5-minute bout duration, 80% inclusion (all days) *Baseline*				
n	160	152		
Mean (SD)	19.8 (20.7)	16.8 (16.5)		
3 months				
n	123	130		
Mean (SD)	19.9 (25.5)	13.5 (15.8)	1.7 (–1.8 to 5.2)	0.350
12 months				
n	120	134		
Mean (SD)	22.0 (25.5)	17.0 (22.4)	1.0 (–3.6 to 5.6)	0.675
MVPA, ≥ 5-minute bout duration, 80% inclusion (weekends) *Baseline*				
n	167	154		
Mean (SD)	14.7 (19.6)	14.9 (18.7)		
3 months				
n	128	139		
Mean (SD)	17.2 (28.9)	11.5 (15.5)	7.0 (2.7 to 11.4)	0.002
12 months				
n	126	137		
Mean (SD)	17.3 (25.2)	14.2 (22.2)	2.3 (–2.3 to 6.9)	0.333

TABLE 17 Accelerometry (all data) (*continued*)

| | Trial arm | | | |
Measure of physical activity	Intervention (*N* = 207)	Control (*N* = 205)	Mean difference (95% CI)	*p*-value
MVPA, > 5-minute bout duration, 80% inclusion (weekdays) *Baseline*				
n	159	153		
Mean (SD)	21.6 (22.8)	17.6 (17.8)		
3 months				
n	125	129		
Mean (SD)	20.6 (25.8)	14.3 (17.7)	0.2 (–3.4 to 3.7)	0.924
12 months				
n	124	136		
Mean (SD)	23.6 (28.7)	18.0 (23.3)	0.4 (–5.0 to 5.9)	0.871
MVPA, ≥ 10-minute bouts, 80% inclusion (all days) *Baseline*				
n	160	152		
Mean (SD)	13.3 (16.8)	11.0 (13.1)		
3 months				
n	123	130		
Mean (SD)	13.3 (20.4)	8.8 (12.6)	2.0 (–0.9 to 4.9)	0.183
12 months				
n	120	134		
Mean (SD)	15.4 (21.7)	11.8 (19.3)	1.5 (–2.5 to 5.5)	0.473
MVPA, ≥ 10-minute bouts, 80% inclusion (weekends) *Baseline*				
n	167	154		
Mean (SD)	9.6 (16.6)	9.6 (14.8)		
3 months				
n	128	139		
Mean (SD)	11.3 (24.9)	7.4 (12.4)	5.6 (2.0 to 9.3)	0.003
12 months				
n	126	137		
Mean (SD)	11.9 (22.1)	9.5 (19.2)	2.2 (–1.8 to 6.2)	0.274
MVPA, ≥ 10-minute bouts, 80% inclusion (weekdays) *Baseline*				
n	159	153		
Mean (SD)	14.4 (18.5)	11.6 (14.8)		
3 months				
n	125	129		
Mean (SD)	13.8 (20.3)	9.5 (14.3)	0.9 (–2.0 to 3.8)	0.552
12 months				
n	124	136		
Mean (SD)	16.6 (24.5)	12.6 (20.1)	1.0 (–3.9 to 6.0)	0.680

Dietary intake as assessed by the Dietary Instrument for Nutrition Education questionnaire

Figures 14–18 depict food intake as assessed by the DINE questionnaire (blue lines denote mean values). The measures (including the categorisations as low, medium and high) are reported in *Table 18*. The baseline self-reported diet of the participants in both groups indicated a high consumption of refined sugar from sugary drinks and low fibre. There was some evidence that alcohol intake had reduced in the intervention arm, although the intake was highly skewed and not robust to alternative models, including non-parametric analyses. No other dietary changes were observed as a result of the intervention or trial participation.
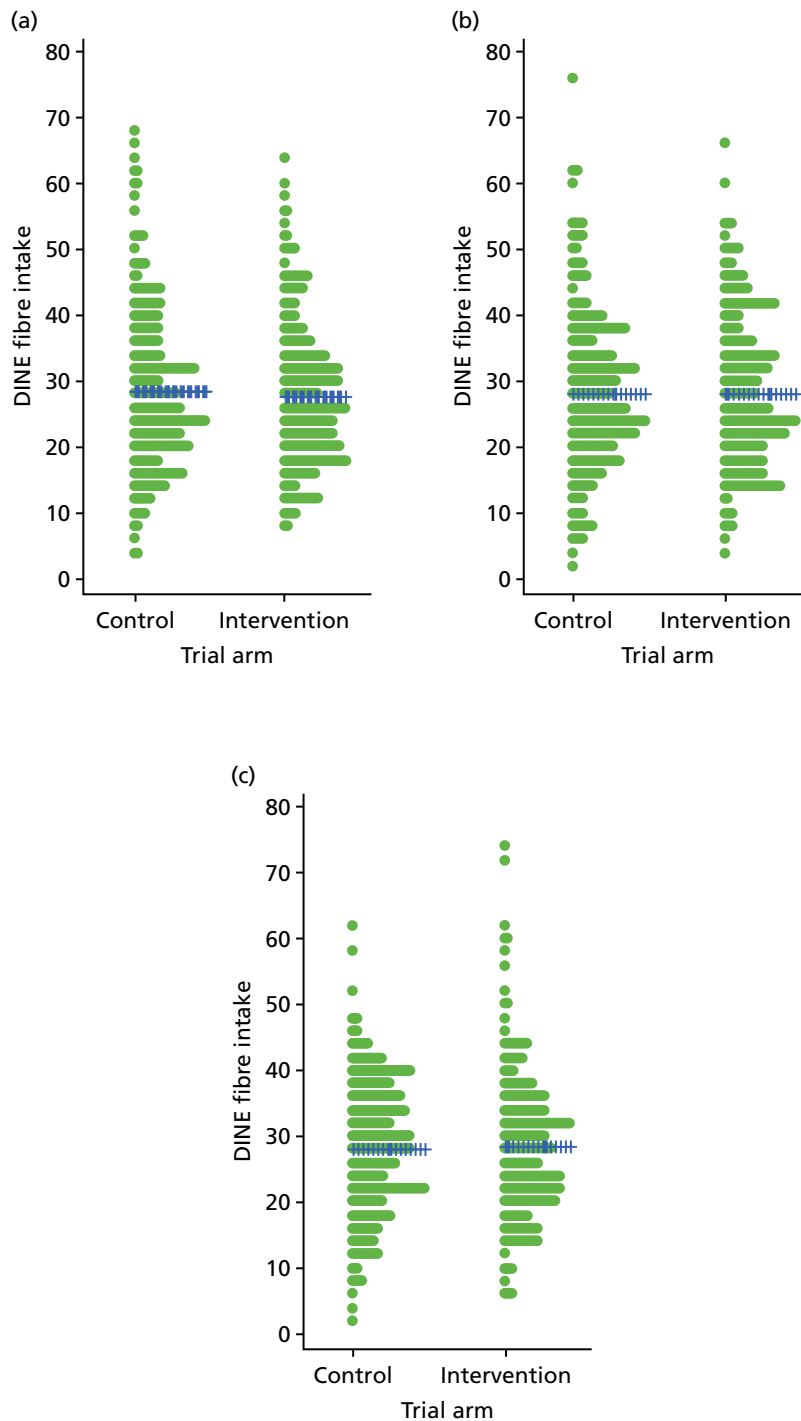
FIGURE 14 Dietary Instrument for Nutrition Education fibre intake. (a) Baseline; (b) 3 months; and (c) 12 months.
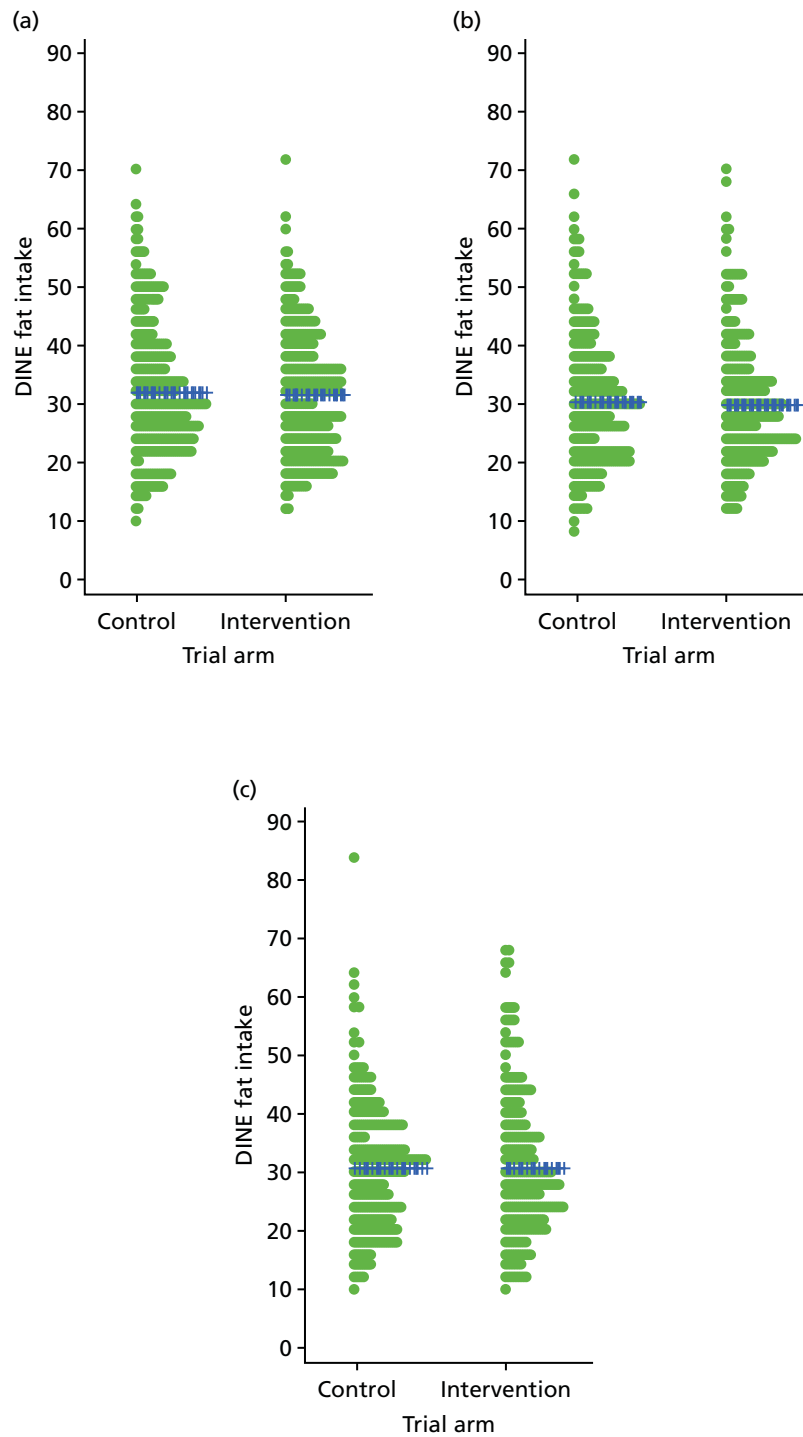
FIGURE 15 Dietary Instrument for Nutrition Education fat intake. (a) Baseline; (b) 3 months; and (c) 12 months.
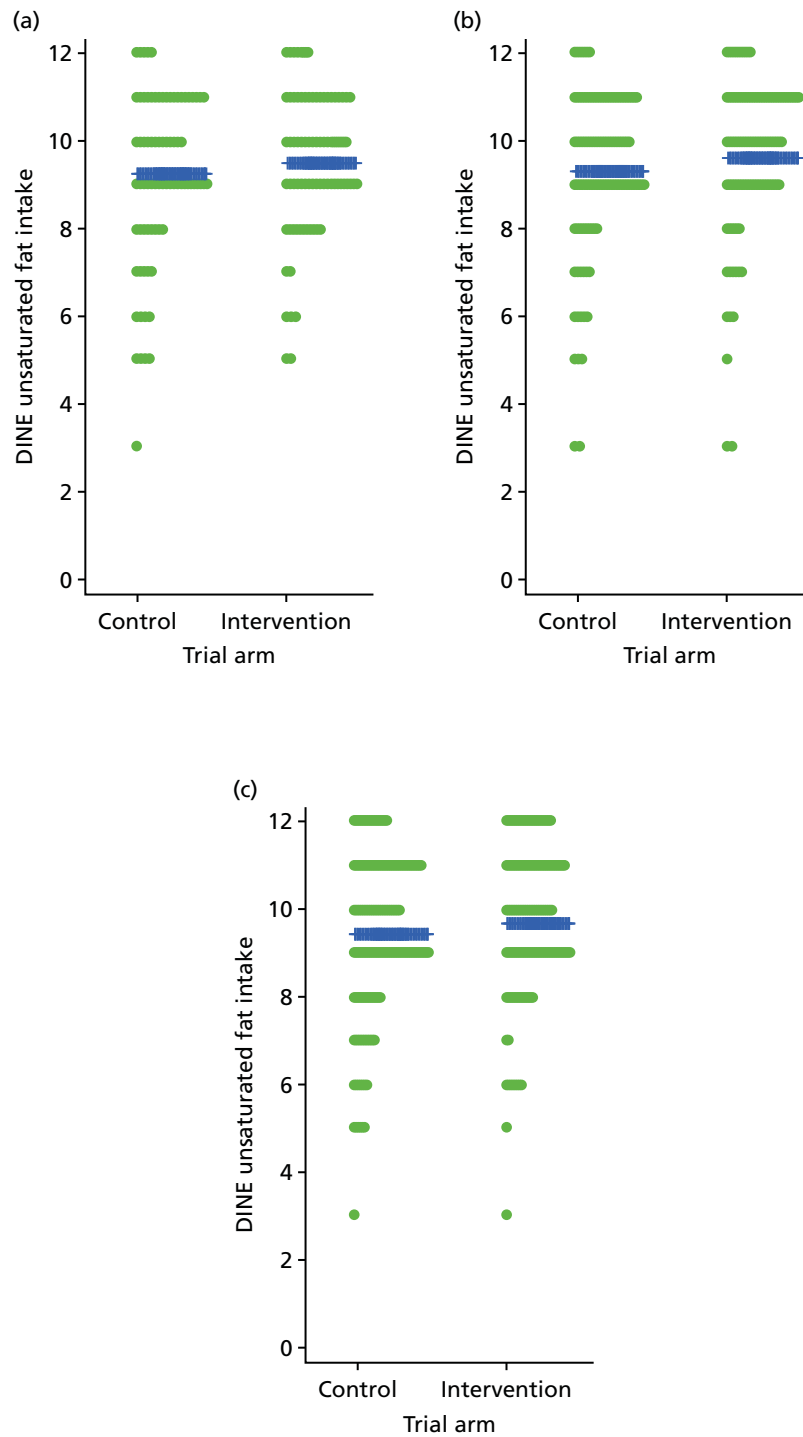
FIGURE 16 Dietary Instrument for Nutrition Education unsaturated fat intake. (a) Baseline; (b) 3 months; and (c) 12 months.
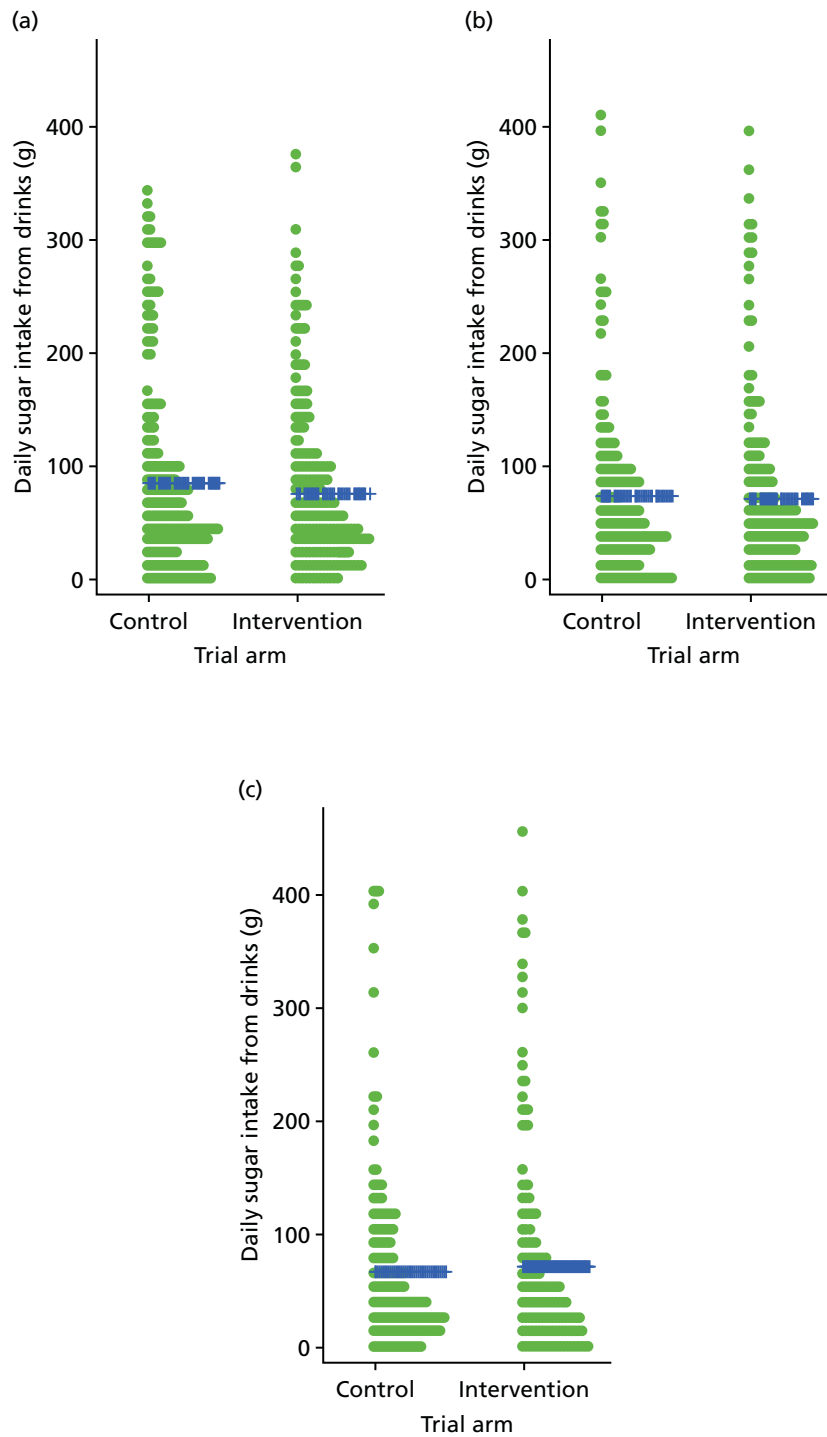
FIGURE 17 Dietary Instrument for Nutrition Education daily sugar intake from drinks (g). (a) Baseline; (b) 3 months; and (c) 12 months.
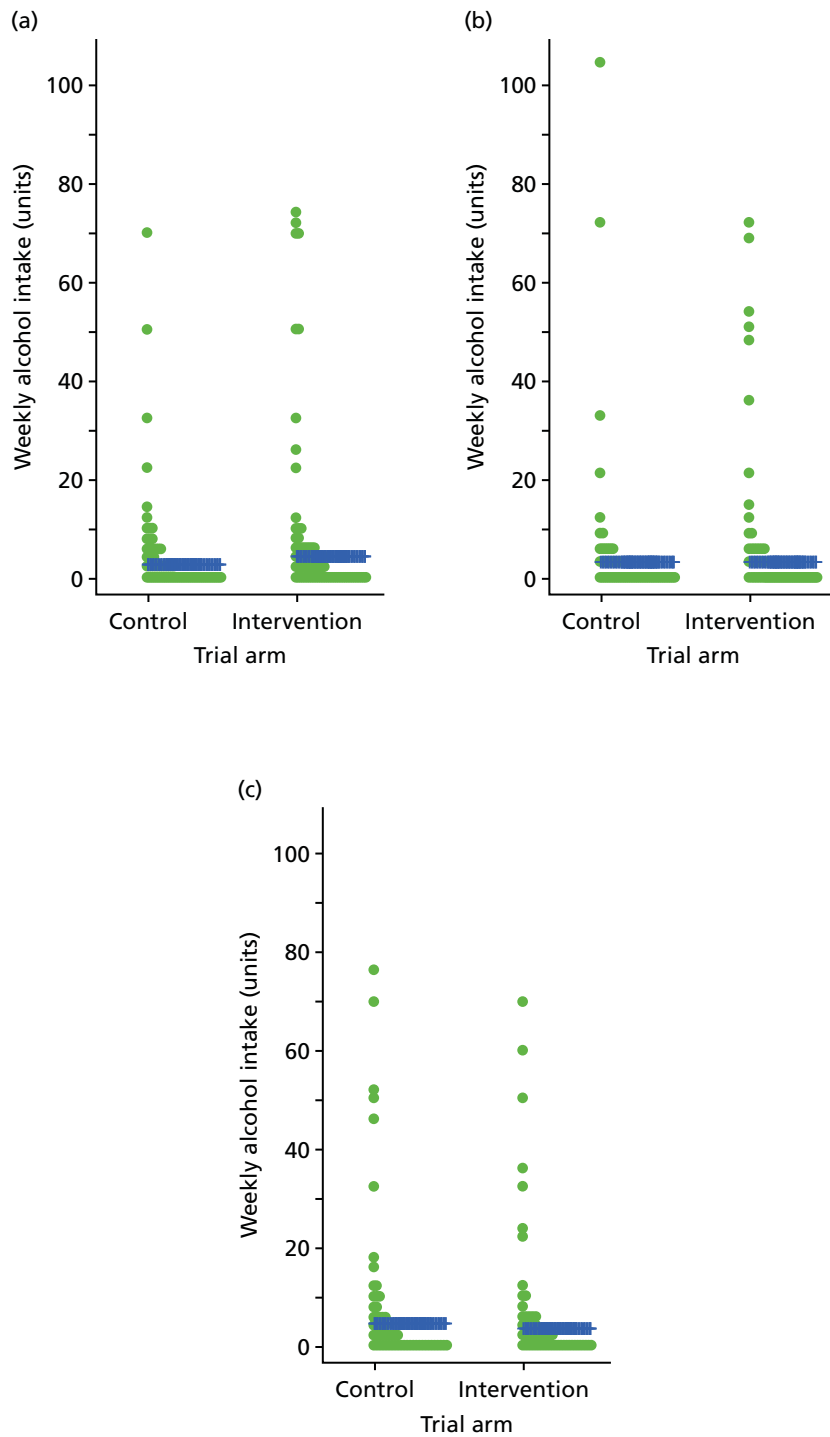
FIGURE 18 Dietary Instrument for Nutrition Education weekly alcohol intake (units). (a) Baseline; (b) 3 months; and (c) 12 months.

TABLE 18 Dietary Instrument for Nutrition Education nutritional intake questionnaire

Dietary intake	Trial arm	
	Intervention (*N* = 207)	Control (*N* = 205)
DINE fibre intake *Baseline*		
n	207	205
Mean (SD)	27.6 (11.3)	28.3 (12.6)
Median (IQR)	26.0 (19.0 to 34.0)	26.0 (20.0 to 36.0)
3 months		
n	178	180
Mean (SD)	28.2 (12.0)	28.0 (12.4)
Median (IQR)	26.0 (19.0 to 36.0)	26.5 (19.5 to 36.0)
12 months		
n	165	172
Mean (SD)	28.6 (12.1)	28.1 (10.6)
Median (IQR)	28.0 (20.0 to 35.0)	28.0 (21.0 to 36.0)
Baseline, n *(%)*		
Low	122 (58.9)	120 (58.5)
Medium	55 (26.6)	50 (24.4)
High	30 (14.5)	35 (17.1)
3 months, n *(%)*		
Low	101 (56.7)	103 (57.2)
Medium	41 (23.0)	53 (29.4)
High	36 (20.2)	24 (13.3)
12 months, n *(%)*		
Low	90 (54.5)	93 (54.1)
Medium	52 (31.5)	61 (35.5)
High	23 (13.9)	18 (10.5)
DINE fat intake *Baseline*		
n	207	205
Mean (SD)	31.5 (11.0)	32.2 (11.9)
Median (IQR)	31.0 (23.0 to 39.0)	30.0 (23.0 to 39.0)
3 months		
n	178	180
Mean (SD)	30.1 (11.4)	30.2 (11.6)
Median (IQR)	28.0 (22.0 to 36.0)	29.0 (21.0 to 37.0)
12 months		
n	165	172
Mean (SD)	30.6 (12.7)	30.6 (11.6)
Median (IQR)	28.0 (22.0 to 37.0)	30.0 (22.0 to 37.5)

TABLE 18 Dietary Instrument for Nutrition Education nutritional intake questionnaire (*continued*)

	Trial arm	
Dietary intake	Intervention (*N* = 207)	Control (*N* = 205)
Baseline, n (%)		
Low	96 (46.4)	96 (46.8)
Medium	65 (31.4)	63 (30.7)
High	46 (22.2)	46 (22.4)
3 months, n (%)		
Low	99 (55.6)	97 (53.9)
Medium	49 (27.5)	52 (28.9)
High	30 (16.9)	31 (17.2)
12 months, n (%)		
Low	90 (54.5)	80 (46.5)
Medium	41 (24.8)	62 (36.0)
High	34 (20.6)	30 (17.4)
DINE unsaturated fat intake *Baseline*		
n	207	204
Mean (SD)	9.5 (1.6)	9.2 (1.9)
Median (IQR)	10.0 (9.0 to 11.0)	9.0 (8.0 to 11.0)
3 months		
n	178	179
Mean (SD)	9.6 (1.9)	9.3 (1.9)
Median (IQR)	10.0 (9.0 to 11.0)	9.0 (9.0 to 11.0)
12 months		
n	164	171
Mean (SD)	9.7 (1.8)	9.4 (1.9)
Median (IQR)	10.0 (9.0 to 11.0)	10.0 (9.0 to 11.0)
Baseline, n (%)		
Low	6 (2.9)	12 (5.9)
Medium	93 (44.9)	94 (45.9)
High	108 (52.2)	98 (47.8)
3 months, n (%)		
Low	6 (3.4)	9 (5.0)
Medium	65 (36.5)	81 (45.0)
High	107 (60.1)	89 (49.4)
12 months, n (%)		
Low	3 (1.8)	7 (4.1)
Medium	68 (41.2)	78 (45.3)
High	93 (56.4)	86 (50.0)

TABLE 18 Dietary Instrument for Nutrition Education nutritional intake questionnaire (*continued*)

Dietary intake	Trial arm	
	Intervention (*N* = 207)	Control (*N* = 205)
Daily sugar intake from drinks (g) *Baseline*		
n	207	205
Mean (SD)	76.2 (73.1)	85.4 (85.1)
Median (IQR)	53.0 (25.0 to 102.0)	56.0 (29.0 to 104.0)
3 months		
n	178	180
Mean (SD)	70.9 (78.9)	74.2 (81.0)
Median (IQR)	49.0 (19.0 to 86.0)	50.0 (22.0 to 93.0)
12 months		
n	165	172
Mean (SD)	71.8 (90.6)	66.3 (77.9)
Median (IQR)	37.0 (12.0 to 90.0)	41.0 (19.0 to 91.0)
Weekly alcohol intake (units) *Baseline*		
n	207	205
Mean (SD)	4.6 (12.6)	3.0 (7.4)
Median (IQR)	0.5 (0.0 to 3.5)	0.5 (0.0 to 3.0)
3 months		
n	178	180
Mean (SD)	3.5 (10.3)	3.5 (12.8)
Median (IQR)	0.0 (0.0 to 2.5)	0.0 (0.0 to 2.5)
12 months		
n	165	172
Mean (SD)	3.7 (9.9)	4.5 (12.2)
Median (IQR)	0.5 (0.0 to 2.5)	0.0 (0.0 to 3.5)

IQR, interquartile range.

Patient-reported outcome measures and disease severity

Health utility (EQ-5D) and QoL (SF-36) are reported in *Tables 19* and *20*. Self-reported QoL post randomisation was generally slightly higher in intervention participants (physical functioning, role limitations), but emotional well-being was slightly higher in the control group participants.

Health utility (EuroQol-5 Dimensions)

The main measure of the EQ-5D-5L showed little difference between groups at either time point, although the 'thermometer' health scale showed a greater improvement among control participants at 12 months, with a difference of 4.4 points ($p = 0.028$).

Health utility (Short Form questionnaire-6 Dimensions)

Self-reported QoL using the SF-36 suggested higher QoL post randomisation in intervention participants for physical functioning and bodily pain, but emotional well-being was higher in the control group (*Table 20*).

TABLE 19 The EuroQol-5 Dimensions

Dimension	Trial arm		Mean difference (95% CI)	*p*-value
	Intervention (*N* = 207)	Control (*N* = 205)		
EQ-5D-5L health utility *Baseline*				
n	206	203		
Mean (SD)	0.793 (0.201)	0.783 (0.187)		
3 months				
n	178	180		
Mean (SD)	0.815 (0.165)	0.785 (0.214)	0.02 (–0.02 to 0.05)	0.259
12 months				
n	165	170		
Mean (SD)	0.793 (0.237)	0.793 (0.239)	–0.02 (–0.06 to 0.03)	0.495
EQ-5D-5L 'thermometer' health state *Baseline*				
n	207	204		
Mean (SD)	57.9 (20.3)	54.4 (20.4)		
3 months				
n	178	180		
Mean (SD)	60.3 (19.8)	57.7 (19.8)	0.1 (–3.1 to 3.3)	0.956
12 months				
n	164	170		
Mean (SD)	58.5 (21.3)	61.6 (21.1)	–4.4 (–8.4 to –0.5)	0.028

TABLE 20 Short Form questionnaire-6 Dimensions

Dimension	Trial arm		Mean difference (95% CI)	*p*-value
	Intervention (*N* = 207)	Control (*N* = 205)		
Physical functioning *Baseline*				
n	207	204		
Mean (SD)	72.8 (25.6)	71.9 (24.6)		
3 months				
n	178	180		
Mean (SD)	76.9 (23.1)	70.9 (26.2)	4.4 (1.0 to 7.9)	0.012
12 months				
n	164	170		
Mean (SD)	76.5 (25.6)	70.9 (26.8)	4.1 (0.2 to 8.0)	0.038

TABLE 20 Short Form questionnaire-6 Dimensions (*continued*)

Dimension	Trial arm		Mean difference (95% CI)	*p*-value
	Intervention (*N* = 207)	Control (*N* = 205)		
Role limitations owing to physical health Baseline				
n	207	204		
Mean (SD)	54.6 (42.0)	54.2 (41.0)		
3 months				
n	178	179		
Mean (SD)	63.8 (39.7)	60.2 (41.3)	3.3 (–4.8 to 11.4)	0.425
12 months				
n	164	169		
Mean (SD)	65.9 (41.8)	60.8 (40.7)	4.8 (–3.0, 12.7)	0.226
Role limitations owing to emotional problems Baseline				
n	207	204		
Mean (SD)	46.2 (42.6)	44.0 (42.3)		
3 months				
n	178	179		
Mean (SD)	52.2 (43.8)	50.1 (44.0)	1.3 (–7.3 to 9.8)	0.770
12 months				
n	164	170		
Mean (SD)	58.5 (43.9)	52.5 (45.4)	5.1 (–3.6 to 13.8)	0.251
Energy/fatigue score Baseline				
n	207	204		
Mean (SD)	43.2 (21.8)	40.5 (23.1)		
3 months				
n	178	180		
Mean (SD)	44.9 (21.6)	42.8 (23.6)	–0.6 (–3.6 to 2.5)	0.720
12 months				
n	164	170		
Mean (SD)	44.9 (22.2)	45.0 (24.6)	–2.7 (–6.3 to 0.9)	0.140
Emotional well-being Baseline				
n	207	204		
Mean (SD)	58.3 (21.4)	56.4 (23.9)		
3 months				
n	178	180		
Mean (SD)	58.8 (22.3)	57.0 (25.3)	–0.1 (–3.5 to 3.3)	0.957
12 months				
n	164	170		
Mean (SD)	58.8 (23.4)	62.2 (23.4)	–5.3 (–9.0 to –1.7)	0.004

TABLE 20 Short Form questionnaire-6 Dimensions (*continued*)

Dimension	Trial arm		Mean difference (95% CI)	*p*-value
	Intervention (*N* = 207)	Control (*N* = 205)		
Social functioning *Baseline*				
n	207	204		
Mean (SD)	60.5 (29.1)	61.2 (28.7)		
3 months				
n	178	180		
Mean (SD)	64.5 (29.6)	62.7 (31.5)	2.8 (–2.7 to 8.4)	0.311
12 months				
n	164	170		
Mean (SD)	66.1 (30.0)	65.7 (29.5)	1.5 (–4.2 to 7.1)	0.615
Bodily pain *Baseline*				
n	207	204		
Mean (SD)	71.6 (28.8)	74.8 (27.4)		
3 months				
n	178	180		
Mean (SD)	75.2 (25.5)	71.3 (28.4)	5.5 (0.9 to 10.2)	0.020
12 months				
n	164	170		
Mean (SD)	71.6 (30.7)	70.6 (29.1)	1.4 (–2.9 to 5.7)	0.534
General health *Baseline*				
n	207	204		
Mean (SD)	45.0 (20.3)	44.8 (20.7)		
3 months				
n	178	180		
Mean (SD)	48.0 (21.8)	46.8 (20.3)	–0.3 (–3.4 to 2.8)	0.846
12 months				
n	164	170		
Mean (SD)	49.8 (23.1)	46.8 (21.4)	2.1 (–1.5 to 5.6)	0.249
Health change *Baseline*				
n	207	204		
Mean (SD)	57.4 (30.2)	57.4 (29.0)		
3 months				
n	178	180		
Mean (SD)	62.1 (26.7)	58.6 (28.9)		
12 months				
n	164	170		
Mean (SD)	62.5 (25.3)	63.4 (26.7)		

Condition perception (Brief Illness Perception Questionnaire)

The B-IPQ measured participants' perceptions of their 'weight' condition. The total score showed a small improvement in both groups over time, although the changes on the eight dimensions of the B-IPQ were mixed. There were no significant differences between groups on the total score or for each of the eight dimensions (*Table 21*).

TABLE 21 Brief Illness Perception Questionnaire

| Perception | Trial arm | | Mean difference (95% CI) | *p*-value |
	Intervention (*N* = 207)	Control (*N* = 205)		
B-IPQ overall total *Baseline*				
n	207	204		
Mean (SD)	5.5 (1.5)	5.5 (1.7)		
3 months				
n	178	180		
Mean (SD)	5.0 (1.7)	5.3 (1.7)	–0.2 (–0.4 to 0.0)	0.110
12 months				
n	164	170		
Mean (SD)	5.0 (1.9)	5.0 (1.7)	–0.0 (–0.3 to 0.3)	0.973
How much does your weight problem affect your life? *Baseline*				
n	207	204		
Mean (SD)	6.1 (2.7)	6.2 (2.8)		
3 months				
n	178	180		
Mean (SD)	5.9 (2.8)	6.1 (2.9)		
12 months				
n	164	170		
Mean (SD)	5.9 (3.0)	5.7 (2.9)		
How long do you think your weight problem will continue? *Baseline*				
n	206	202		
Mean (SD)	6.1 (2.5)	6.0 (2.7)		
3 months				
n	176	180		
Mean (SD)	5.9 (2.4)	5.9 (2.6)		
12 months				
n	163	169		
Mean (SD)	5.7 (2.7)	5.6 (2.9)		

TABLE 21 Brief Illness Perception Questionnaire (*continued*)

Perception	Trial arm		Mean difference (95% CI)	*p*-value
	Intervention (*N* = 207)	Control (*N* = 205)		
How much control do you feel you have over your weight problem? Baseline				
n	207	204		
Mean (SD)	4.4 (2.6)	4.1 (2.9)		
3 months				
n	178	180		
Mean (SD)	5.4 (2.5)	4.7 (2.8)		
12 months				
n	164	170		
Mean (SD)	5.4 (2.6)	4.9 (3.0)		
How much do you think lifestyle programmes can help your weight problem? Baseline				
n	206	203		
Mean (SD)	7.2 (2.1)	6.7 (2.6)		
3 months				
n	178	180		
Mean (SD)	6.8 (2.7)	5.9 (2.7)		
12 months				
n	163	170		
Mean (SD)	6.5 (2.7)	6.0 (3.0)		
How much do you experience symptoms from your weight problem? Baseline				
n	207	204		
Mean (SD)	5.4 (3.0)	5.2 (3.1)		
3 months				
n	178	180		
Mean (SD)	4.6 (3.0)	4.7 (3.2)		
12 months				
n	162	170		
Mean (SD)	4.9 (3.2)	4.5 (3.2)		
How concerned are you about your weight problem? Baseline				
n	207	204		
Mean (SD)	7.6 (2.6)	7.4 (2.7)		
3 months				
n	178	180		
Mean (SD)	7.0 (2.9)	7.0 (2.8)		
12 months				
n	164	170		
Mean (SD)	6.8 (2.8)	6.4 (3.2)		

TABLE 21 Brief Illness Perception Questionnaire (*continued*)

Perception	Trial arm		Mean difference (95% CI)	*p*-value
	Intervention (*N* = 207)	Control (*N* = 205)		
How well do you feel you understand your weight problem? *Baseline*				
n	207	204		
Mean (SD)	6.4 (2.8)	6.7 (2.8)		
3 months				
n	178	180		
Mean (SD)	7.2 (2.6)	6.8 (2.8)		
12 months				
n	164	170		
Mean (SD)	7.1 (2.7)	6.8 (2.9)		
How much does your weight problem affect you emotionally? *Baseline*				
n	207	204		
Mean (SD)	6.1 (2.9)	6.1 (3.4)		
3 months				
n	178	180		
Mean (SD)	5.5 (3.3)	6.0 (3.4)		
12 months				
n	164	170		
Mean (SD)	5.3 (3.2)	5.2 (3.2)		

Psychiatric well-being (Brief Psychiatric Rating Scale and Patient Health Questionnaire-9)

Tables 22 and *23* show scores on the observer-rated BPRS and the patient-completed PHQ-9. The baseline scores of the BPRS of around 30 indicate 'mild illness', and the differences between the groups and over time were not clinically significant (see *Table 22*). *Table 23* shows the percentage of participants who scored above the clinical cut-off point (i.e. ≥ 10) for depression on the PHQ-9 at each time point. Although the percentage who scored above the cut-off point reduced in both groups between baseline

TABLE 22 Brief Psychiatric Rating Scale

BPRS	Trial arm		Mean difference (95% CI)	*p*-value
	Intervention (*N* = 207)	Control (*N* = 205)		
Baseline				
n	207	204		
Mean (SD)	30.9 (8.8)	31.5 (9.4)		
3 months				
n	178	180		
Mean (SD)	30.3 (9.0)	30.4 (9.4)	0.2 (–1.3 to 1.7)	0.827
12 months				
n	165	170		
Mean (SD)	29.1 (9.7)	28.3 (9.5)	1.0 (–0.9 to 2.9)	0.303

TABLE 23 Patient Health Questionnaire-9

PHQ-9 scores	Trial arm		Mean difference (95% CI)	*p*-value
	Intervention (*N* = 207)	Control (*N* = 205)		
Baseline				
n	207	204		
Mean (SD)	10.6 (6.3)	11.0 (6.8)		
PHQ-9 score of ≥ 10, *n* (%)	106 (51.2)	116 (56.9)		
3 months				
n	178	180		
Mean (SD)	10.3 (6.3)	10.1 (7.1)	0.5 (–0.4 to 1.3)	0.314
PHQ-9 score of ≥ 10, *n* (%)	94 (52.8)	94 (52.2)		
12 months				
n	165	170		
Mean (SD)	9.9 (7.0)	9.6 (6.6)	0.5 (–0.4 to 1.5)	0.299
PHQ-9 score of ≥ 10, *n* (%)	74 (44.8)	79 (46.5)		

and 12 months, there were no significant differences between the groups. The mean baseline scores on the PHQ-9 were in the moderate depressive symptom range, and again the differences between the groups and over time were not clinically significant (see *Table 23*).

Smoking status
At baseline, approximately half of the participants were current smokers (*Table 24*). Smoking rates did not change during the trial in either group.

TABLE 24 Smoking status

Smoking status	Trial arm, *n* (%)	
	Intervention (*N* = 207)	Control (*N* = 205)
Baseline		
Smoking status	N = *207*	N = *205*
Current smoker	98 (47.3)	108 (52.7)
Light smoker	18 (8.7)	20 (9.8)
Moderate smoker	37 (17.9)	32 (15.6)
Heavy smoker	43 (20.8)	55 (26.8)
Amount not reported	0 (0.0)	1 (0.5)
Offered help to stop smoking	89 (47.3)	90 (47.1)
Brief intervention	38 (20.2)	53 (27.7)
Nicotine replacement	58 (30.9)	61 (31.9)
Drug treatment	3 (1.6)	4 (2.1)
Electronic cigarettes/vape	5 (2.7)	3 (1.6)
Other types	8 (4.3)	6 (3.1)

TABLE 24 Smoking status (*continued*)

Smoking status	Trial arm, *n* (%)	
	Intervention (*N* = 207)	Control (*N* = 205)
Currently using therapy to stop smoking	24 (12.8)	25 (13.1)
Nicotine replacement	15 (8.0)	013 (6.8)
Drug treatment	0	0
Electronic cigarettes/vape	10 (5.3)	12 (6.3)
Other types	9 (4.8)	12 (6.3)
3 months		
Smoking status	N = *178*	N = *180*
Current smoker	85 (47.8)	96 (53.3)
Light smoker	13 (7.3)	19 (10.6)
Moderate smoker	28 (15.7)	31 (17.2)
Heavy smoker	44 (24.7)	46 (25.6)
Offered help to stop smoking	78 (47.0)	71 (42.5)
Brief intervention	39 (23.5)	39 (23.4)
Nicotine replacement	55 (33.1)	54 (32.3)
Drug treatment	4 (2.4)	2 (1.2)
Electronic cigarettes/vape	5 (3.0)	1 (0.6)
Other types	2 (1.2)	2 (1.2)
Currently using therapy to stop smoking	21 (12.7)	19 (11.4)
Nicotine replacement	11 (6.6)	13 (7.8)
Drug treatment	0	0
Electronic cigarettes/vape	10 (6.0)	6 (3.6)
Other types	9 (5.4)	6 (3.6)
12 months		
Smoking status	N = *166*	N = *172*
Current smoker	75 (45.2)	88 (51.2)
Light smoker	17 (10.2)	13 (7.6)
Moderate smoker	29 (17.5)	27 (15.7)
Heavy smoker	29 (17.5)	48 (27.9)
Offered help to stop smoking	64 (45.1)	63 (42.9)
Brief intervention	27 (19.0)	27 (18.4)
Nicotine replacement	47 (33.1)	42 (28.6)
Drug treatment	1 (0.7)	3 (2.0)
Electronic cigarettes/vape	3 (2.1)	3 (2.0)
Other types	6 (4.2)	2 (1.4)
Currently using therapy to stop smoking	22 (15.4)	11 (7.5)
Nicotine replacement	12 (8.4)	6 (4.1)
Drug treatment	0	0
Electronic cigarettes/vape	10 (7.0)	4 (2.7)
Other types	9 (6.3)	5 (3.4)

Weight loss programmes

During the trial, 25 participants [(7.4%) eight control, 17 intervention] reported attending one or more weight loss programmes outside the trial (*Table 25*).

Ten-year cardiovascular and diabetes risk

The Framingham cardiovascular risk scores are presented in *Table 26*. Twenty-six participants in each trial arm had a pre-existing cardiovascular diagnosis and 84 (40 intervention, 44 control) were aged < 30 years; the Framingham risk score is not defined for these subgroups. The mean 'desk' Framingham 10-year risk (which does not incorporate laboratory measures) was 10.9% for the intervention group and 10.6% for the control group at baseline, and remained similar at both 3 months and 12 months. The mean laboratory-based Framingham scores were substantially lower in the control group at baseline (7.7% vs. 8.6%), and both demonstrated minor change (< 1%) at 12 months. Only one participant in the intervention arm developed a cardiac event during the trial; this individual died.

Table 27 shows that 60 participants (35 in the intervention group and 25 in the control) group had diabetes on entry to the trial. Among the remainder, the 10-year risk of developing diabetes was 17.2% in both trial arms at baseline, with over half being in the 'moderate' risk category. By 12 months, the risk had decreased by 0.5% in the intervention arm and by 0.4% in the control arm. No participant was recorded as having developed diabetes during the trial, although one participant (intervention arm) was hospitalised twice because of diabetes-related complications.

Change in medications

During the trial, the vast majority of participants remained on antipsychotics (*Table 28*), although around one-fifth of participants in both groups experienced a change of antipsychotic treatment. Approximately

TABLE 25 Weight loss programmes

	Trial arm	
Use of weight loss programme	**Intervention (*N* = 207)**	**Control (*N* = 205)**
3 months *Followed up*	N = *178*	N = *180*
Attended any weight loss programme	4 (2.5%)	8 (4.4%)
Slimming World® (Alfreton, UK)	2	1
Weight Watchers® (New York, NY, USA)	0	3
Structured programme organised by GP/care team	1	3
Other	1	1
12 months *Followed up*	N = *165*	N = *170*
Attended any weight loss programme	17 (10.3%)	8 (4.7%)
Slimming World	8	3
Weight Watchers	4	1
Structured programme organised by GP/care team	3	4
Other	4	0

Notes
Some participants attended more than one weight loss programme.
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TABLE 26 Ten-year cardiovascular risk (Framingham)

Risk measure	Trial arm		Mean difference (95% CI)	*p*-value
	Intervention (*N* = 207)	Control (*N* = 205)		
Aged 30–74 years and no cardiovascular condition, *n* (%)	142 (68.6)	136 (66.3)		
Framingham % cardiovascular risk score (excluding laboratory measures)				
Baseline				
n	142	135		
Mean (SD)	10.9 (9.5)	10.6 (10.9)		
3 months				
n	123	120		
Mean (SD)	10.8 (8.6)	10.7 (10.5)		
Change at 3 months				
n	123	120		
Mean (SD)	–0.5 (3.8)	–0.5 (4.4)	0.0 (–0.8 to 0.9)	0.986
12 months				
n	114	123		
Mean (SD)	10.9 (9.6)	10.5 (10.5)		
Change at 12 months				
n	112	118		
Mean (SD)	–0.3 (3.9)	–0.3 (4.4)	–0.1 (–1.1 to 1.0)	0.905
Framingham % cardiovascular risk score: including laboratory measures				
Baseline				
n	120	117		
Mean (SD)	8.7 (8.2)	7.6 (6.3)		
12 months				
n	100	105		
Mean (SD)	8.6 (7.7)	7.6 (6.3)		
Change at 12 months				
n	87	90		
Mean (SD)	–0.7 (4.0)	–0.4 (4.1)	–0.2 (–1.2 to 0.8)	0.690

TABLE 27 Ten-year diabetes mellitus risk

| Risk measure | Trial arm | | Mean difference (95% CI) | *p*-value |
	Intervention (*N* = 207)	Control (*N* = 205)		
Has diabetes mellitus, *n* (%)	35 (16.9)	25 (12.2)		
Diabetes UK 10-year diabetes mellitus risk (%)				
Baseline				
n	171	180		
Mean (SD)	17.2 (6.2)	17.2 (6.2)		
Diabetes UK 10-year diabetes mellitus risk group, n (%)				
Low	3 (1.5)	6 (2.9)		
Increased	65 (31.6)	68 (33.3)		
Moderate	111 (53.9)	109 (53.4)		
High	27 (13.1)	21 (10.3)		
Diabetes UK 10-year diabetes mellitus risk (%): 3 months				
n	150	159		
Mean (SD)	16.8 (6.1)	17.3 (6.2)		
Change at 3 months				
n	150	159		
Mean (SD)	–0.1 (1.8)	–0.1 (1.8)	–0.0 (–0.4 to 0.3)	0.940
Diabetes UK 10-year diabetes mellitus risk group: 3 months, n (%)				
Low	5 (2.8)	5 (2.8)		
Increased	57 (32.0)	58 (32.0)		
Moderate	97 (54.5)	100 (55.2)		
High	19 (10.7)	18 (9.9)		
Diabetes UK 10-year diabetes mellitus risk (%): 12 months				
n	141	154		
Mean (SD)	16.6 (6.6)	16.9 (6.6)		
Change at 12 months				
n	141	154		
Mean (SD)	–0.5 (2.8)	–0.4 (2.9)	0.0 (–0.7 to 0.8)	0.896
Diabetes UK 10-year diabetes mellitus risk group: 12 months, n (%)				
Low	9 (5.4)	10 (5.8)		
Increased	54 (32.1)	54 (31.2)		
Moderate	86 (51.2)	89 (51.4)		
High	19 (11.3)	20 (11.6)		

TABLE 28 Changes in medication

	Trial arm, *n* (%)	
Psychiatric medication	Intervention (*N* = 207)	Control (*N* = 205)
Antipsychotics		
Antipsychotics changed by 3 months	9 (5.0)	21 (11.6)
Antipsychotics changed by 12 months	24 (14.3)	29 (16.7)
Antidepressants		
On antidepressants at 3 months	112 (62.9)	111 (61.3)
Antidepressants changed by 3 months	11 (6.1)	10 (5.5)
On antidepressants at 12 months	111 (66.1)	105 (60.7)
Antidepressants changed by 12 months	29 (17.3)	27 (15.4)

half of participants in both groups were treated with antidepressants. By the end of the trial, 17% of intervention arm participants and 15% of control arm participants had experienced a change of antidepressant medication.

Session feedback forms and centre outcomes

Session feedback
Intervention group participants could provide anonymous feedback following each group session. It was not possible to link feedback to their clinical outcomes, but the feedback could be linked to the study centre results. Seven hundred and eight session feedback forms were returned after the seven group sessions across the 10 centres, although we did not know who responded or on how many occasions. Therefore, the numbers and percentages in the tables below are based on 'forms returned' rather than on 'participants'. Five of the returned forms had no study centre identifiers and were excluded. When two responses were indicated (*n* = 3), the higher score was taken, and missing responses (*n* = 10) were replaced with the mean of the participants' other responses.

Table 29 shows that the vast majority of responses were positive for all six statements, with almost 90% 'agreeing' with each statement either 'strongly' or scoring '2' on a Likert scale of 5. A total of 87.2% of participants strongly agreed or agreed that the sessions had met their needs.

Participants had the opportunity to add comments to their forms, although only four did so. Three of these comments were positive:

> I felt this has been a fantastic group and really looking forward to meeting up in 3 months' time.

> One thing that went well? Talking together about different weight control.

> What went well. Everything except the cold.

The only negative comment made was:

> Mental health as bad as ever which affects my answer.

Session feedback by study centre

Session feedback scores could range from 6 to 30, with 6 indicating the most positive response on all five items and 30 indicating the most negative response on all items. *Table 29* shows the average feedback scores across the 10 centres and *Table 30* shows the average scores by centre. Feedback was similar across the centres: in most centres > 50% of forms recorded the most positive score of 6 and in all centres at least 75% of forms recorded scores below 12 (equivalent to scoring 2 for each statement). There were no

TABLE 29 Session feedback questions and responses overall (*n* = 703 for each question)

	Responses (%)				
	1	2	3	4	5
Question	**(strongly agree)**		**(neither agree nor disagree)**		**(strongly disagree)**
The facilitator listened to me	77.1	12.5	2.0	2.0	6.4
I understood what we talked about	74.4	13.9	3.0	2.3	6.4
I found what we talked about useful	71.8	17.1	2.7	2.6	5.8
I felt the facilitator understood the challenges I face	66.1	20.3	5.1	3.0	5.4
What we talked about made sense to me	76.7	12.4	2.4	3.3	5.3
Overall the session met my needs	67.3	19.9	4.7	3.1	5.0

Note

TABLE 30 Session feedback scores (*n* = 703) by centre

		Total score			Score of, %	
Site	**Number of forms returned**	**Mean (SD)**	**Median**	**IQR**	**6 (most positive)**	**> 24 (most negative)**
Sheffield	51	7.9 (4.3)	7	6–8	47.1	3.9
Leeds and York	39	8.1 (4.2)	6	6–10	64.1	2.6
Bradford	70	10.6 (8.5)	6	6–11	58.6	15.7
Manchester	84	7.7 (3.6)	6	6–9	61.9	1.2
South London	61	10.1 (7.1)	6	6–11	54.1	8.2
Sussex	105	9.6 (5.8)	7	6–11	45.7	5.7
Southern Health	116	9.2 (6.3)	6	6–9	57.8	7.8
Devon	69	9.7 (7.0)	6	6–10	56.5	10.1
Somerset	26	7.6 (3.0)	6	6–8	65.4	0
Cornwall	82	9.9 (6.1)	8	6–11	41.5	7.3
Overall[a]	703	9.2 (6.1)	6	6–10	54.1	6.8

IQR, interquartile range.
a   All centres have at least 75% of forms scoring below 12 (equivalent to scoring 2 for each statement).
Note

significant correlations between mean weight change and mean feedback scores for centres, at 3 months or 12 months (Spearman's rank-order correlation = –0.20; $p = 0.476$, and Spearman's rank-order correlation = 0.042; $p = 0.454$, respectively).

Adverse events

The adverse events are summarised in *Table 31*. Most were expected and related to the psychiatric illness. The majority were hospitalisations for psychiatric reasons. Serious adverse events were assessed for relatedness and two were considered to be possibly related to the intervention, as described below.

Thirty-six participants (20 in the intervention group and 16 in the control group) were admitted to hospital for mental health reasons (specified as 'expected' in the protocol) during the trial. One admission was deemed to be possibly trial related; the patient was admitted following a relapse after stopping their medication in an attempt to control their weight. The participant was randomised to the intervention arm, but did not attend any of the sessions.

Four participants (two in each trial arm) were reported to have attempted suicide (specified as 'expected' in the protocol) and 21 participants were hospitalised (11 in the intervention group and 10 in the control group) for non-mental health-related reasons. None of these events was considered to be related to the study procedures.

Participant deaths

Four deaths were reported, all in the intervention group. Three deaths occurred during the trial and one occurred several months after the trial ended. Detailed information is given below.

Patient 1 was a 53-year-old white man with a BMI of 34 kg/m^2 and concurrent diagnoses of asthma and depression, who had been on antipsychotic medication for 32 years. His death occurred 264 days after randomisation, after he had attended four foundation sessions and two booster sessions. The cause of death was a pulmonary embolism, which is likely to have developed secondarily to a ruptured Achilles tendon.

TABLE 31 Adverse events summary

| | Trial arm | | | |
| | Intervention (*N* = 207) | | Control (*N* = 205) | |
Adverse event	Number of events	Number (%) of participants	Number of events	Number (%) of participants
Any adverse event	46	37 (17.9)	34	26 (12.7)
Psychiatric hospitalisation	23	20 (9.7)	17	16 (7.8)
Self-harm	0		1	1 (0.55)
Suicide attempt	2	2 (1.0)	2	2 (1.0)
Hospitalisation (not mental health related)	13	11 (5.3)	11	10 (4.9)
Death	3	3 (1.4)	0	
Skin reaction to accelerometer	4	4 (1.9)	0	
Other	1	1 (0.5)	3	3 (1.5)

Prior to the study, the participant reported walking a lot, achieving more than 10,000 steps per day, as assessed by pedometer. Objective accelerometry data indicated that he had not changed his physical activity after the intervention. Nevertheless, as a ruptured Achilles tendon could have occurred as a result of following advice from the intervention, the relationship was reported to the ethics committee as possibly intervention related. This death was therefore reported within 15 days to the research ethics committee, which determined that no further action was required.

Patient 2 was a 48-year-old white woman with a BMI of 40 kg/m^2 and concurrent diagnoses of hypertension and dyslipidaemia. She had been taking antipsychotic medication for 22 years. Her death occurred 260 days after randomisation, after she had attended three foundation sessions. The cause of death was determined by the coroner as 1a) left ventricular hypertrophy, 1b) hypertension and obesity. The death was unrelated to the intervention.

Patient 3 was a 35-year-old black woman with a BMI of 38 kg/m^2 and a concurrent diagnosis of type 2 diabetes mellitus who had been on antipsychotic medication for 7 years. Her death occurred 57 days after randomisation after four foundation sessions. Her diabetes mellitus had been treated with oral antidiabetes agents, but not sodium–glucose co-transporter-2 inhibitors. She was found unresponsive at her home and the death was determined as resulting from diabetic ketoacidosis leading to cardiac arrest. The death was unrelated to the intervention.

Patient 4 was a 36-year-old Asian woman with a BMI of 36 kg/m^2 and a concurrent diagnosis of type 2 diabetes mellitus who had been taking antipsychotic medication for 10 years. She died from a myocardial infarction 1 month after she completed the study, while she was detained under section 3 of the Mental Health Act 1983.[111] She had been under the care of the local cardiology team, which advised that she stop taking clozapine, which precipitated the deterioration in her mental health. The death was unrelated to the intervention.

Chapter 5 Results of the process evaluation

Context

Context, sometimes defined as 'settings, roles, interactions and relationships',[112] affects the implementation of complex interventions. *Figure 19* shows contextual factors that affect the implementation of, and engagement with, the STEPWISE intervention, coded in accordance with the ICF conceptual framework.[76]

Health condition: schizophrenia, with antipsychotic-induced weight gain

Body structure/function
Impairment
Many people with schizophrenia function well most of the time, but some will be dealing with impairments of the following functions:
• b117 Intellectual
• b122 Global psychosocial
• b130 Energy and drive
• b132 Emotional
• b140 Attention
• b144 Memory
• b156 Perceptual
• b160 Thought
• b164 Higher-level cognitive
• b167 Language

Activity
Activity limitation
• d155 Acquiring skills
• d166 Reading
• d175 Solving problems
• d210 Undertaking a single task
• d310 Communicating with – receiving – spoken messages
• d330 Speaking
• d470 Using transportation
• d5701 Managing diet and fitness
• d5702 Maintaining one's health
• d620 Acquisition of goods and services
• d630 Preparing meals

Participation
Participation restriction
• d730 Relating with strangers
• d7200 Forming relationships
• d750 Informal social relationships
• d7504 Informal relationships with peers
• d850 Remunerative employment
• d870 Economic self-sufficiency

Environmental factors
• e325 Support from peers
• e410 Individual attitudes of immediate family members
• e450 Individual attitudes of health professionals
• e460 Societal attitudes
• e580 Health services, systems and policies

Personal factors
• Age
• Gender
• Socioeconomic status
• Region
• Family status
• Coping styles
• Personality traits

FIGURE 19 Context understood through the ICF conceptual framework. Reprinted from the WHO's *Towards a Common Language for Functioning, Disability and Health ICF*;[76] diagram entitled 'model of disability' on page 9. WHO reference number: WHO/EIP/GPE/CAS/01.3. Copyright 2002.

Body functions

Half of the facilitators interviewed commented that, although most participants were receptive to the intervention, an individual's psychosocial functioning could affect how well they could engage with STEPWISE. Facilitators discussed this most frequently in terms of the transient severity of hallucinatory or delusional symptoms associated with paranoid schizophrenia; some also spoke of comorbid learning disabilities, implying problems with attention, memory, goal-directed/logical thought, insight, executive function or language, which are commonly associated with disorganised-type schizophrenia:

> . . . when we've gone out together we've all been discussing . . . university degrees they've got . . . they are really quite intelligent people but they still do have a psychotic illness . . . they could be distracted if there's something on their mind, or if they're paranoid at the time . . . that has to be taken into consideration a little bit more when you're planning.
>
> *Facilitator S03/F02*

> We've got quite a small group and one of the persons in the group . . . he has a mild learning difficulty and I'm not sure that he's quite sort of clear about what, why he's there particularly sometimes, which is difficult.
>
> *Facilitator S06/F05*

> I think some of them have mild learning disabilities and umm I'm not sure that you know they take in everything we tell them in the session.
>
> *Facilitator S09/F01*

> There could be like mild learning disabilities running alongside their mental illness as well and that, I have definitely noticed that that's hindered . . . someone's ability to engage.
>
> *Facilitator S09/F03*

In addition, developers characterised this group as sometimes less interactive than other populations and occasionally somnolent or impulsive:

> . . . there's been a couple of occasions where people do seem a bit overmedicated . . . Asleep . . . or saying very random things that really have no you know no connection to what is being talked about.
>
> *Developer D05*

> We all said that the medication that we're on, different people different reactions, but quite a few of them said you know, I'm sluggish from the sedation. And it's hard to wake you up in the morning.
>
> *Participant S08/Q06*

> . . . so when the sandwiches came out there was definitely some people [sic.] it was literally . . . automatic that reaching for sandwiches and eating and reaching for another sandwich . . . and thinking do you know, 'have you noticed how many of those sandwiches that you've eaten?'.
>
> *Developer D03*

Activities and participation

Cognitive problems meant that some participants had problems learning and applying knowledge, specifically, acquiring skills, reading and problem-solving. Undertaking tasks could take longer than expected, and that could be difficult:

> We did have to sort of adjust to the people that were in the group . . . the ones that were struggling with the reading . . . we would just sort of put more time in with them.
>
> *Facilitator S09/F01*

Costs notwithstanding, facilitators felt that the use of taxis was essential for attendance; the barriers to using transportation were great for those with severe symptoms or poor cognition, and many lived in areas that were poorly served by public transport. Aside from managing diet and fitness, the principal objective of STEPWISE, a self-care theme that often arose was the importance of adherence to antipsychotic medication in the face of weight gain:

> Quite a few service users get put off continuing to take their medication because of the side effects and this gives them a way to control it so it isn't only kind of benefiting their physical health, but it will benefit their mental health as well if it's helping them to stay on the medication.
>
> *Facilitator S06/F01*

In some cases, family or residential care staff were responsible for shopping and food preparation. Meeting strangers and forming and conducting informal social relationships could cause anxiety. Some had never met others with their condition; others talked about the difficulty of discussing antipsychotic-induced weight gain at Weight Watchers owing to the stigma of mental illness:

> . . . they are finally coming in to a group of people they have never met. It's quite anxiety provoking for them, isn't it?
>
> *Facilitator S06/F04*

> So, the STEPWISE programme was really the first time I had had exposure to other service users.
>
> *Participant S09/Q01*

> I would never have said anything [at Weight Watchers] about my medication sort of being a contributor to me putting on weight because they'd say 'What is it?' and . . . I would've felt pressure to tell them. And then it was like a 'oh no I've told them I'm mentally ill now' sort of thing.
>
> *Participant S10/Q03*

Many STEPWISE attendees were not in remunerative employment and some were living in economically difficult circumstances:

> You end up having more of a sedentary lifestyle because you're told you're not fit to work.
>
> *Participant S08/Q09*

> I was struck by some of the levels of deprivation . . . there was somebody who was living in a caravan. Their caravan had been washed away in the floods so they actually didn't have anywhere to live . . . they were there at the group, which was pretty amazing, but if you think about . . . where this fits on their . . . continuum of needs . . . some people are just getting by.
>
> *Developer D03*

Environmental factors

The attitudes of family members were not always supportive vis-à-vis lifestyle changes, and stigmatising treatment by other members of the public was reported:

> They found these sessions were the opportunity for them do it for themselves instead of having someone else there . . . [one of] the participants brought someone with them . . . it was a relative and you could see, there was a lot of . . . judgemental attitude, like, 'oh, you should be doing this,' or, 'you shouldn't be doing that,' and . . . 'why are you doing this?' and it was a lot of pressure on that participant.
>
> *Developer 01*

The individual attitudes of facilitators were characterised by developers as being generally sensitive to the needs of an autonomy-enabled approach to behaviour change, with only a small minority being overly didactic in delivery. The following quotation from a facilitator is illustrative of how many facilitators characterised their roles, interactions and relationships with clients:

> *Going to an acute [psychiatric] ward and you're saying to the person take these tablets, they'll turn around and say to you, 'why should I?' Whereas, if you've got somebody who's got a general illness they just sit there and put them in their mouth [laughs] . . . you get used to having to discuss things with people and in that respect I suppose it was natural for me to do things that way [i.e. in accordance with the STEPWISE philosophy] . . . you've got to be more open-minded, I think, with people with mental health . . . a lot of the people you're talking to are extremely intelligent people and so therefore you do respect them . . . they're not an illness, they're a person [with] need, wants feelings, ways of doing things . . .*
>
> *Facilitator S03/F02*

However, some facilitators thought that health professionals who were meant to be referring patients to STEPWISE ('gatekeepers') sometimes erected barriers to patient engagement:

> *A lot of clinicians have said their clients don't like group work or they don't like to leave their home and they've put a lot of barriers in the way of people engaging.*
>
> *Facilitator S06/F01*

Interviewees described the availability of, and referral patterns associated with, existing lifestyle interventions as ad hoc, fragmented and locally idiosyncratic, often involving referral to other organisations. This was confirmed by our survey of usual care.[36] Monitoring of weight was not systematic for this population in all trusts, and, although all trusts talked about physical health as a priority, scarcity of resources was a problem, although quality-improvement initiatives were changing this in some cases (see also *Sense-making*, *Operational work* and *Appraisal work*).

How context might affect the success of the intervention

Facilitator views of STEPWISE and *Implementation process* concentrate on how organisational context affects outcome. To more vividly illustrate and explore potential context effects (see also *Table 4*), we present six vignettes of interviewees from the intervention arm who experienced clinically important weight gain (*Box 1*) and weight loss (*Box 2*). These vignettes suggest that, although weight control is possible in people with first episode psychosis and in people living in the most deprived neighbourhoods (S04/Q02), it is particularly difficult for those with first episode psychosis (S04/Q08, S04/Q12, S07/Q06). Those with clinically important weight loss may have less severe psychiatric symptoms and comorbidities (S04/Q02; BPRS score of 34) than those with clinically important weight gain (S04/Q08; BPRS score of 44). Those who experienced clinically important weight loss generally talk about needing more ongoing support or, especially, closer monitoring of behaviour change enactment and outcomes, as if they are more alert to the risk of relapse.

The intervention's theory of change

As part of the process evaluation, the intervention development team at LDC was asked to use a behaviour change techniques taxonomy[25,95] to identify active ingredients within the STEPWISE intervention (*Table 32*).[95,113] Although the STEPWISE intervention is inspired by a range of behaviour change theories, in conversation with LDC staff, we established that it has a systematic basis in three in particular.[114] The first is self-efficacy theory (*Figure 20*), which posits that the central mechanism behind behaviour change is a person's belief that they can change.[85] Interventions can boost those beliefs by confronting someone with personal experiences of their success, other people's experiences of success, verbal persuasion about their capability and arousing their emotions. The second theory, the self-regulatory model of illness behaviour (*Figure 21*), proposes that the interpretation of symptoms and social messages, coping strategies and the appraisal of their effectiveness

BOX 1 Intervention interviewees who experienced clinically important weight gain

---

S04/Q08

Woman, 32 years old, ethnic white British, unemployed, neighbourhood in the 20% most deprived. Gained 13.6 kg in the first 3 months and a further 16.1 kg thereafter (total weight gain of 29.7 kg). Diagnosed comorbidities: depression, asthma and an alcohol problem; first-degree relatives with diabetes mellitus or a heart condition. First episode psychosis (2 years since diagnosis). BPRS score of 44 (moderately ill). Moderately severe somatic concern, anxiety and hallucinatory behaviour. Moderate depressive mood. Mild suspiciousness. Very mild emotional withdrawal, conceptual disorganisation, tension, mannerisms, hostility, motor retardation, unco-operativeness, blunted affect and excitement. Reported a high level of acceptability of the intervention, focusing on self-monitoring and social support elements, but wanted more sessions. Enjoyed small group size owing to self-reported anxiety. Reported losing weight during the foundation course but putting on weight thereafter. Reported using the taxis provided, despite living 5 minutes' drive from the venue.

S04/Q12

Man, 30 years old, ethnic Indian, unemployed, neighbourhood in the 10% most deprived. Gained 4.3 kg in the first 3 months and a further 1.2 kg thereafter (total weight gain of 5.5 kg). No comorbidities. First episode psychosis (2 years since diagnosis). BPRS score of 26 (mildly ill). Moderate motor retardation. Mild emotional withdrawal and blunted affect. Very mild unco-operativeness. Reported finding the intervention acceptable, but remarked 'I think it needed more talking about . . . all you can do in the gym, like, to lose weight faster'. Preferred smaller groups.

S07/Q06

Man, 25 years old, ethnic white British, unemployed, neighbourhood in the 50% most deprived. Gained 8.4 kg in the first 3 months and a further 2.9 kg thereafter (total weight gain of 11.3 kg). First episode psychosis (9 months since diagnosis). Diagnosed with depression and irritable bowel syndrome. BPRS score of 34 (mildly ill). Severe hallucinatory behaviour. Moderate anxiety, guilty feelings, depressive mood. Mild somatic concern. Focused on dietary aspects of the intervention only.

BOX 1 Intervention interviewees who experienced clinically important weight gain

BOX 2 Intervention interviewees who experienced clinically important weight loss

---

S04/Q02

Woman, 33 years old, ethnic African, unemployed, neighbourhood in the 10% most deprived. Gained 1.2 kg in the first 3 months and lost 7.3 kg thereafter (total weight loss of 6.1 kg). Diagnosed with hypertension and depression. First episode psychosis (7 months since diagnosis). BPRS score of 34 (mildly ill). Moderate somatic concern and blunted affect. Mild anxiety, emotional withdrawal, unco-operativeness. Very mild guilty feelings, mannerisms, depressive mood, suspiciousness. 'It needs to be longer . . . maybe like 10 weeks . . . give us updates on how we are coping, on what we are doing . . . to monitor us more closely . . . it was becoming a routine and then it just stopped . . . the questions were important because they, we needed to know if there's any downfalls . . . challenges . . .'.

S03/Q06

Man, 35 years old, ethnic white British, unemployed, neighbourhood in the 10% most deprived. Lost 3.8 kg in the first 3 months and lost a further 13.4 kg thereafter (total weight loss of 17.2 kg). Diagnosed with asthma. ICD-10 F20. BPRS score of 34 (mildly ill). Moderate emotional withdrawal, blunted affect. Mild somatic concern, anxiety, conceptual disorganisation, depressive mood. Very mild guilty feelings, tension. 'It helped . . . [to] be aware of my eating habits . . . it's important to do exercise in order to lose the weight . . . it's been quite a lot of time in between doing the course and the refresher course . . . so I'm feeling a bit less motivation with the dieting'.

S08/Q05

Woman, 28 years old, ethnic white British, unemployed, neighbourhood in the 50% most deprived. Gained 1.5 kg in the first 3 months and lost a further 10.8 kg thereafter (total weight loss of 9.3 kg). Diagnosed with having an alcohol problem. ICD-10 F25. BPRS score of 41 (moderately ill). Moderately severe anxiety, hallucinatory behaviour, unusual thought content. Mild somatic concern, hostility. Very mild emotional withdrawal, guilt feelings, tension, grandiosity, depressive mood, suspiciousness, blunted affect. Talked in compelling detail about enactment of exercise strategies, demonstrating understanding and application of STEPWISE content; also, talked about the need for, 'more regular support . . . see how you're doing, because . . . the next session's quite far away'.

---

all interact, and are all targets for intervention.[115] The third and final theory, the relapse prevention model (*Figure 22*), aims to maintain abstinence from problem behaviours by helping the client to develop coping responses and perceived self-efficacy.[116] On a day-to-day basis, the LDC team talked rather more about empowerment philosophy than the three behaviour change theories. Empowerment philosophy is 'based on the premise that human beings have the capacity to make choices and are responsible for the consequences of their choices'.[117] It is also the difference between what drives the style of delivery; empowerment philosophy maintains that people are autonomous decision-makers and not purely driven by information provision. Self-reflection supports change, whereas behaviour change theory supports the content of the intervention. It is better understood as a conceptual model rather than a middle-range theory[118] of the kind associated with health psychology and behaviour change,[114,119] being comparatively vague in terms of how change is to be effected. The section above, *How context might affect the success of the intervention*, and the vignettes in *Box 2* suggest that some participants might welcome more sustained support, so care must be taken to ensure that empowerment does not translate to a demand for patients to self-manage in isolation.[120,121]

TABLE 32 Behaviour change techniques/theoretical constructs mapped to the STEPWISE programme components

Behaviour change techniques	Behaviour change theory: construct	Demonstrated in the programme
1. Goals and planning		
1.1 Goal-setting behaviour	SET: VE (modelling)	• Next steps (sessions 1–3)
	SET: VP (suggestion; self-instruction)	• Next steps (session 4) • Booster sessions 1–3
	SET: OE	
	CSM: coping procedures (approach)	
	RP: coping	
1.2 Problem-solving	SET: VE (modelling)	• Sharing stories (sessions 2–4)
	SET: VP (suggestion; self-instruction)	• Sharing stories (booster sessions 1–3) • Keeping it going (booster sessions 1–3)
	CSM: coping procedures (approach)	• Next steps (session 4) • Next steps (booster sessions 1–3)
	RP: coping	
1.4 Action-planning	SET: VE (modelling)	• Next steps (session 4)
	SET: VP (suggestion; self-instruction)	• Booster sessions next steps 1–3
	CSM: coping procedures (approach)	
	RP: coping	
1.5 Review behaviour goals	SET: VE (modelling)	Sharing stories asks to review goals but not specifically reset unless it is revisited in the 'next steps' (sessions 2–4, booster sessions 1–3)
	SET: VP (suggestion; self-instruction)	
	SET: EA (symbolic exposure/desensitisation)	
	CSM: appraisal	
	RP: review behaviour goals	
2. Feedback and monitoring		
2.3 Self-monitoring of behaviour	SET: EME (performance exposure; self-instructed performance)	Encourage use of food diaries/pedometers and physical activity diaries
	SET: VP (self-instruction)	• Session 1: topic 1B – food diary • Session 2: topic 2B – physical activity diary and pedometer
	SET: EA (symbolic exposure)	
	CSM: appraisal	
	CSM: coping procedures (approach)	Encouraged to complete and use these tools throughout the whole programme
	RP: self-monitoring	• Revisited in booster sessions 1–3 • Revisited in telephone calls
	RP: behaviour assessment	
2.4 Self-monitoring of outcomes of behaviour	SET: EME (performance exposure; self-instructed performance); VP (self-instruction)	• Given weighing scales and encouraged to record their weight weekly (session 1)
	CSM: appraisal	
	CSM: coping procedures (approach)	

TABLE 32 Behaviour change techniques/theoretical constructs mapped to the STEPWISE programme components (*continued*)

Behaviour change techniques	Behaviour change theory: construct	Demonstrated in the programme
3. Social support		
3.1 Social support (unspecified)	CSM: coping procedures (approach)	● Telephone calls to provide direct support ● Promote the person to work out where they can get support (query if coded here)
4. Shaping knowledge		
4.1 Instruction on how to perform the behaviour	SET: VE (symbolic modelling) SET: VP (suggestion)	● Pedometer use (from session 2 onwards) ● Provide recipes in handbook: for booster session 1
4.2 Information about antecedents	SET: EME (performance exposure) SET: VE (live and symbolic modelling) CSM: emotion (food diary) CSM: emotion (high risk) RP: self-monitoring	● Food diary (from session 2 onwards) ● High-risk situations in booster sessions 1–4
4.4 Behavioural experiments	SET: EME (self-instructed performance) SET: OE SET: VE (live and symbolic modelling) CSM: appraisal	● Explore how people have tested new behaviours ● Sharing stories (sessions 2–4, booster sessions 1–3); new behaviours explored through programmes – snacks (topic 2, session 4), drinks (topic 1b, session 1), eating out (topic 4a, session 4)
5. Natural consequences		
5.1 Information about health consequences	SET: VE (symbolic modelling) SET: PAS (symbolic exposure) SET: OE CSM: illness representations RP: education about effects of substance	● Your story: consequences of weight gain elicited (session 1) ● Physical activity: benefits elicited (session 2) ● Sedentary behaviour: benefits (session 3) ● Booster session 2: physical activity
5.6 Information about emotional consequences	SET: VE (symbolic modelling) SET: VP (suggestion) SET: PAS (attribution, symbolic exposure) SET: OE CSM: ER	● Benefits of increased physical activity and decreased sedentary behaviour (sessions 2 and 3 and booster session 2) ● Improved mood ● Gains: elicited in 'next steps' (sessions 1–4 and booster sessions 1–3). Query if coded

TABLE 32 Behaviour change techniques/theoretical constructs mapped to the STEPWISE programme components (*continued*)

Behaviour change techniques	Behaviour change theory: construct	Demonstrated in the programme
6. Comparison of behaviour		
6.2 Social comparison	SET: VE (live and symbolic modelling) SET: OE	• Sharing stories: various comparisons with others in the group (sessions 2–4, booster sessions 1–3) • Next steps: others' plans (all sessions) • In other sessions [e.g. drinks/snacks/physical activity (topic 1b, 2a and 2b, sessions 1–2)]
7. Associations		
7.1 Prompts	CSM: coping procedure (approach) RP: coping	• Mindfulness stickers (booster sessions 3) • Food diaries (session 2)
7.4 Remove access to the reward	SET: VE (live and symbolic modelling) VP (self-instruction) RP: reminder – what to do if you slip	• Keeping it going: strategies on avoiding high-risk situations (booster sessions 1–3)
8. Repetition and substitution		
8.2 Behavioural substitution	SET: VP (suggestion; self-instruction) CSM: coping procedure (approach)	Prompt group to come up with these throughout programme: • snacks (session 2) • drinks (session 1) • sedentary behaviour (session 3) • mindfulness (booster session 3) • eating out (session 4)
8.4 Habit reversal	SET: VP (suggestion; self-instruction) CSM: coping procedure (approach)	Elicit from group/person alternatives to behaviours: snack, drinks, physical activity, sedentary behaviour (sessions 1, 2 and 3)
8.6 Generalisation of target behaviour	SET: EME CSM: coping procedure (approach)	Mindfulness – advised to put the magnet on the fridge Looking at menus (session 3 or 4)
8.7 Graded tasks	SET: EME (performance exposure) SET: VP (suggestion; self-instruction)	• 100-calorie game (session 3) • Physical activity: increasing steps/intensity/frequency (session 2) TheraBand (TheraBand® resistance band; TheraBand, Akron, OH, USA): physical activity revisited (booster session 2)
9. Comparison of outcomes		
9.1 Credible source	SET: VP (suggestion)	• National guidelines: physical activity sessions (session 2, booster sessions 2); sedentary behaviour (session 3); plate model (session 3) • Health-care professionals
10. Reward and threat		
10.7 Self-incentive	SET: INCENTIVE CSM: coping procedure (approach coping)	• Session 4: making a plan • All booster sessions
10.9 Self-reward	SET: VP (suggestion; self-instruction) CSM: coping procedure (approach coping)	Encourage self-praise in the 'sharing stories' section

TABLE 32 Behaviour change techniques/theoretical constructs mapped to the STEPWISE programme components (*continued*)

Behaviour change techniques	Behaviour change theory: construct	Demonstrated in the programme
11. Regulation		
11.2 Reduce negative emotions	SET: VE (live and symbolling modelling) EA: (attribution; symbolic exposure; symbolic desensitisation) CSM: ER CSM: coping procedure (approach coping) RP: stress management	• Sharing stories: strategies elicited (sessions 2–4, booster sessions 1–3) • Challenges and what might help (all sessions) • Flip charts: medication and your weight (topic 1a, session 1)
12. Antecedents		
12.1 Restructuring physical environment	RP: skills training	Keeping it going (booster sessions 1–3)/sharing stories – high-risk situations – strategies to manage (not having a big bag of crisps – not buying things in the first place) Magnet on the fridge
12.2 Restructuring social environment	RP: skills training	Keeping it going (booster sessions 1–3)
12.3 Avoidance/reducing exposure to cues for behaviour	SET: VP (self-instruction) Relapse prevention model RP: skills training	Keeping it going (booster sessions 1–3)
12.4 Distraction	SET: VP (self-instruction; suggestion) RP	Keeping it going (booster sessions 1–3); sharing stories (sessions 1–4; all booster sessions)
13. Identity		
13.2 Framing/reframing	CSM: IR RP: cognitive restructuring	Keeping it going (booster sessions 1–3)
14. Self-belief		
14.1 Verbal persuasion about capacity	SET: VP (suggestion; self-instruction) RP: cognitive restructuring	Elicit (*not tell*) how they might challenge self-doubts • Sharing stories (sessions 2–4, booster sessions 1–3) • Next steps (sessions 1–4, booster sessions 1–3) • Keeping it going (booster sessions 1–3)
14.3 Focus on past success	SET: EME CSM: appraisal RP: behaviour assessment	• Sharing stories: elicit past successes (sessions 2–4, booster sessions 1–3) • Next steps (sessions 1–4)

CSM, common-sense model; EA, emotional arousal; EME, enactive mastery experience; ER, emotional representations; IR, illness representations; OE, outcome expectancy; PAS, physical and affective states; RP, relapse prevention model; SET, self-efficacy theory; VE, vicarious experience; VP, verbal persuasion.

| Sources of self-efficacy | Modes of induction with BCTs | Self-efficacy theory |

Participant modelling
• 15.3 Focus on past success

Performance desensitisation
• 15.3 Focus on past success

Performance exposure
• 2.3 Self-monitoring of behaviour
• 2.4 Self-monitoring of outcomes of behaviour
• 4.2 Information about antecedents
• 8.7 Graded tasks • 15.3 Focus on past success

Self-instructed performance
• 2.3 Self-monitoring of behaviour
• 2.4 Self-monitoring of outcomes of behaviour
• 4.4 Behavioural experiments
• 15.3 Focus on past success

Performance accomplishments

Live modelling
• 1.1 Goal-setting behaviour • 1.2 Problem-solving
• 1.4 Action-planning • 1.5 Review behaviour goals
• 4.2 Information about antecedents
• 4.4 Behavioural experiments • 6.2 Social comparison • 7.4 Remove access to the reward

Symbolic modelling
• 1.1 Goal-setting behaviour • 1.2 Problem-solving
• 1.4 Action-planning • 1.5 Review behaviour goals
• 4.1 Instruction on how to perform the behaviour
• 4.2 Information about antecedents
• 4.4 Behavioural experiments • 5.1 Information about health consequences • 5.6 Information about emotional consequences • 6.2 Social comparison • 7.4 Remove access to the reward

Vicarious experience

Symbolic modelling
• 1.1 Goal-setting behaviour • 1.2 Problem-solving
• 1.4 Action-planning • 1.5 Review behaviour goals
• 4.1 Instruction on how to perform the behaviour
• 5.6 Information about emotional consequences
• 8.2 Behavioural substitution • 8.4 Habit reversal
• 8.7 Graded tasks • 9.1 Credible source
• 10.7 Self-incentive • 10.9 Self-reward
• 11.2 Reduce negative amotion • 12.4 Distraction
• 15.1 Verbal persuasion about capacity

Self-instruction
• 1.1 Goal-setting behaviour • 1.2 Problem-solving
• 1.4 Action-planning • 1.5 Review behaviour goals
• 2.3 Self-monitoring of behaviour • 2.4 Self-monitoring of outcomes of behaviour • 7.4 Remove access to the reward • 8.2 Behavioural substitution • 8.4 Habit reversal • 8.7 Graded tasks • 10.7 Self-incentive • 10.9 Self-reward • 11.2 Reduce negative emotion • 12.3 Avoidance/reducing exposure to cues for behaviour • 12.4 Distraction • 15.1 Verbal persuasion about capacity

Verbal persuasion

Self-instruction
• 11.2 Reduce negative emotion

Symbolic desensitisation
• 1.5 Review behaviour goals • 5.6 Information about emotional consequence • 11.2 Reduce negative emotion

Symbolic exposure
• 1.5 Review behaviour goals • 5.1 Information about health consequence • 5.6 Information about emotional consequences • 11.2 Reduce negative emotion

Emotional arousal

Person

Efficacy expectations

Behaviour

Outcome expectations
• 1.1 Goal-setting
• 4.4 Behavioural experiments
• 5.1 Information about health consequences
• 5.6 Information about emotional consequences
• 6.2 Social comparison

Outcome

FIGURE 20 Use of self-efficacy theory in the STEPWISE intervention. BCT, behaviour-change theories.

FIGURE 21 Use of the common-sense model in the STEPWISE intervention.

When we mapped participant views on the intervention to behaviour change wheel intervention functions (*Table 33*), we found that the majority focused on education, enablement (concordant with the developers' views) and environmental restructuring (reflecting the fact that the topic guide asked about the support tools). A minority of participants (*n* = 8) talked about STEPWISE in terms of persuasion, but four of these were from the subset of people who experienced clinically important weight loss (*n* = 7).

When we mapped participant views on the intervention to behaviour change technique categories (*Table 34*), we found that the majority of interviews could be coded to feedback and monitoring, social support, shaping knowledge and antecedents (again, reflecting the salience of the support tools). The only participants for whom behaviour change techniques in the 'identity' category were salient were again from the subset of people who experienced clinically important weight loss (*n* = 3/7).

Participant acceptability

Affective attitude
The majority of participants felt that the intervention was acceptable, mentioning that lunch, support tools (e.g. weighing scales) and being in a group were helpful.
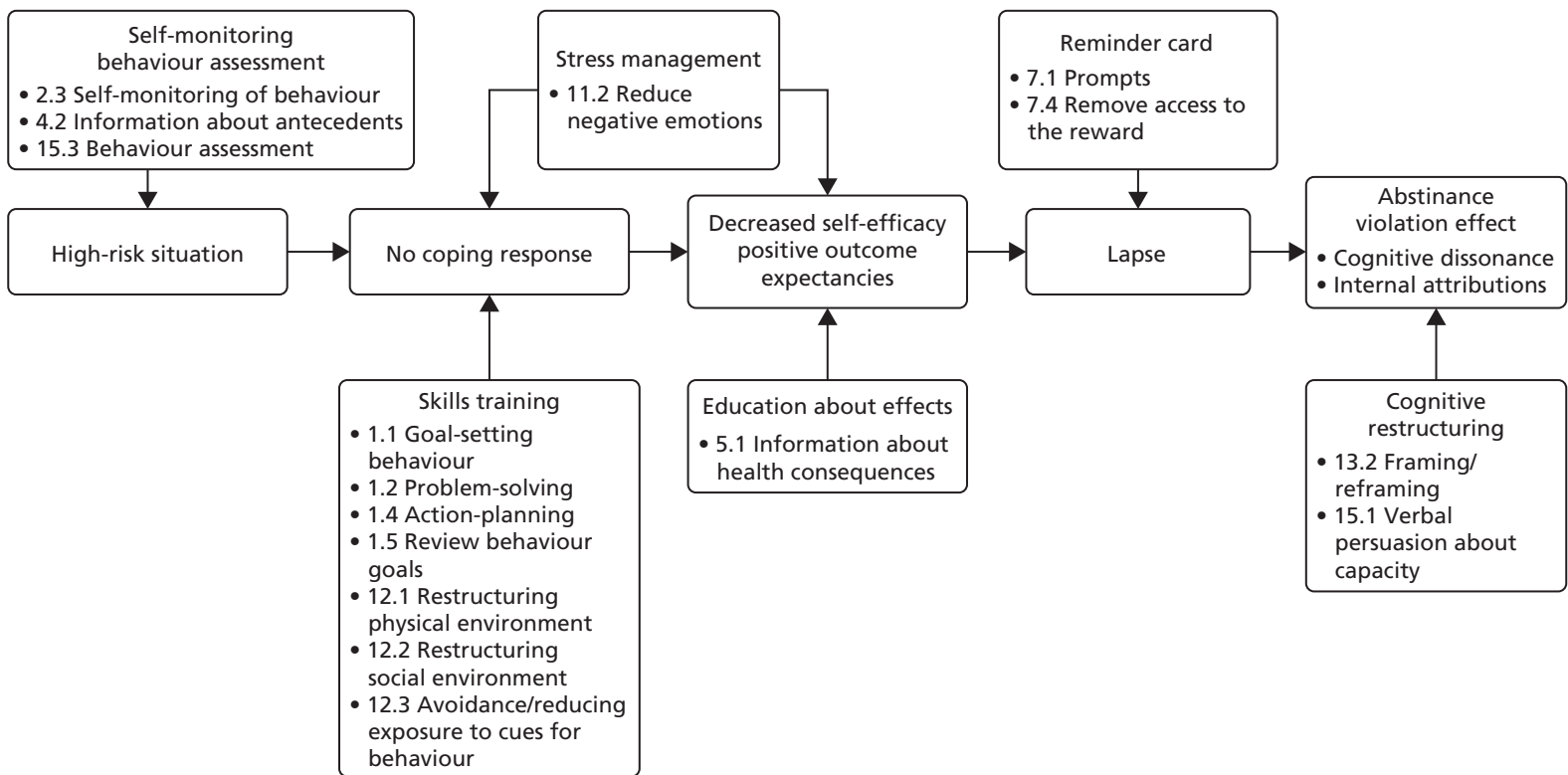
FIGURE 22 Use of the relapse prevention model in the STEPWISE intervention.

TABLE 33 Intervention functions discussed by interviewed participants

Study identifier	Function						
	Education	Enablement	Environmental restructuring	Incentivisation	Modelling	Persuasion	Training
Intervention developers							
D01	•	•	?	?	•	?	•
D02	•	•	–	–	•	?	•
D03	•	•	•	?	•	?	•
D04	•	•	?	•	•	•	•
D05	•	•	•	•	•	•	•
D06	•	•	–	•	•	•	•
D07	•	•	?	?	•	?	•
Participants							
Clinically important weight loss over 12 months							
S03/Q06	•	•	–	–	–	•	•
S01/Q01	•	•	•	–	•	•	•
S08/Q05	•	•	•	–	•	•	–
S04/Q02	•	•	–	–	–	–	–
S06/Q01	–	•	•	–	–	–	•
S01/Q05	•	•	•	–	•	–	•
S02/Q04	•	•	•	–	•	•	•
Weight loss that is not clinically important							
S10/Q03	•	•	•	–	•	–	•
S04/Q09	•	•	–	–	–	–	–
S09/Q04	•	•	•	–	–	–	–
S09/Q02	•	•	•	–	•	–	–
S08/Q06	•	•	•	–	–	•	•
S01/Q04	•	•	•	–	•	–	•
Weight gain that is not clinically important							
S05/Q03	•	•	•	–	•	•	–
S06/Q02	•	•	–	–	•	–	–
S03/Q01	•	•	•	–	–	–	•
S04/Q10	•	–	–	–	–	–	•
S08/Q09	•	•	•	•	–	–	•
S09/Q01	–	•	•	–	•	–	–
Clinically important weight gain							
S04/Q12	•	•	–	–	•	•	–
S07/Q06	•	•	•	–	–	–	–
S04/Q08	•	•	–	–	–	–	–
Qualitative participants without weight data							
S04/Q06	•	•	–	–	•	•	–
S06/Q06	•	•	–	–	•	–	•

•, Present; –, absent; ?, uncertain.

TABLE 34 Behaviour change theory categories discussed by interviewed participants

Study identifier	Category															
	01. Goals and planning	02. Feedback and monitoring	03. Social support	04. Shaping knowledge	05. Natural consequences	06. Comparison of behaviour	07. Associations	08. Repetition and substitution	09. Comparison of outcomes	10. Reward and threat	11. Regulation	12. Antecedents	13. Identity	14.0 Scheduled consequences	15.0 Self-belief	16. Covert learning
Clinically important weight loss over 12 months																
S03/Q06	•	•	•	•	–	–	–	–	–	–	–	•	•	–	–	–
S01/Q01	•	–	•	•	–	•	•	•	–	–	–	•	•	–	–	–
S08/Q05	•	•	•	•	•	•	•	–	–	–	–	•	•	–	–	–
S04/Q02	–	–	•	•	–	–	–	–	–	–	–	–	–	–	–	–
S06/Q01	–	•	•	–	–	–	–	•	–	–	–	•	–	–	–	–
S01/Q05	•	•	•	•	•	•	–	•	–	–	–	•	–	–	–	–
S02/Q04	•	•	•	•	–	•	–	–	–	–	–	•	–	–	–	–
Weight loss that is not clinically important																
S10/Q03	–	•	•	–	•	•	–	•	–	–	–	•	–	–	–	–
S04/Q09	–	•	•	–	–	–	–	–	–	–	–	–	–	–	–	–
S09/Q04	–	•	–	•	•	–	•	•	–	–	–	•	–	–	–	–
S09/Q02	–	•	•	•	•	–	–	•	–	–	–	•	–	–	–	–
S08/Q06	–	•	–	•	•	–	–	•	–	–	–	•	–	–	–	–
S01/Q04	•	•	–	•	•	–	–	•	–	–	–	•	–	–	–	–
Weight gain that is not clinically important																
S05/Q03	•	–	•	–	•	•	–	–	–	–	–	•	–	–	–	–
S06/Q02	•	•	•	•	•	•	–	–	–	–	–	•	–	–	–	–
S03/Q01	–	•	–	•	•	–	–	•	–	–	–	•	–	–	–	–
S04/Q10	–	–	–	•	•	–	–	–	–	–	–	•	–	–	–	–
S08/Q09	–	•	•	•	•	–	–	•	–	–	–	•	–	–	–	–
S09/Q01	–	•	–	–	–	•	–	–	–	–	–	•	–	–	–	–

TABLE 34 Behaviour change theory categories discussed by interviewed participants (*continued*)

Study identifier	Category															
	01. Goals and planning	02. Feedback and monitoring	03. Social support	04. Shaping knowledge	05. Natural consequences	06. Comparison of behaviour	07. Associations	08. Repetition and substitution	09. Comparison of outcomes	10. Reward and threat	11. Regulation	12. Antecedents	13. Identity	14.0 Scheduled consequences	15.0 Self-belief	16. Covert learning
Clinically-important weight gain																
S04/Q12	•	•	•	–	•	–	•	–	–	–	–	•	–	–	–	–
S07/Q06	–	•	–	•	•	–	–	•	–	–	–	•	–	–	–	–
S04/Q08	–	•	•	–	–	–	–	–	–	–	–	–	–	–	–	–
Qualitative participants without weight data																
S04/Q06	•	•	•	–	•	•	–	–	–	–	–	•	–	–	–	–
S06/Q06	•	•	•	•	•	–	•	•	–	–	–	•	–	–	–	–

•, Present; –, absent.

Intervention coherence

Participants described the facilitators as welcoming, realistic and flexible and that they appeared to be confident. Some participants said that the facilitators helped their understanding and made the intervention more accessible:

> Well it's very friendly and informal, um and you could ask questions at any time. Um, I've tried to go to Weight Watchers . . . in the past, and it is quite awkward to sort of stop and say hang on a minute, what, 'what did you mean about that' . . . STEPWISE was really easy to understand and was put in a way that you could sort of take away with you sort of thing.
>
> *Participant S10/Q03*

Burden

Participants generally felt that the length and frequency of sessions was acceptable and the intervention did not require significant effort to take part; however, several participants wanted more sessions (8–12) or more time within a session ($\approx$3 hours):

> Interviewer: *Yeah. And what might that have erm, obviously if you'd have had the sessions for a couple of months, what would that have . . . given you?*
>
> Participant S04/Q08: *Erm a bit more of a boost, erm like because at the minute I've been like, when I was going there, I was losing weight and since I've like not been going I've been like putting weight on. And like, not been like sticking to my routine and me diet and stuff like that, so it was giving me more confidence and more help and getting me out of me house and me flat and stuff like that so. Erm this month's not been going, I've been like comfort eating, so, it got me out more.*
>
> Yeah it's a bit tedious . . . too much time teaching people how to cook eggs to be fair . . . Not knocking the facilitators, they delivered it quite well but the material was patronising . . .
>
> *Participant S04/Q09*

> . . . the way that it was set out and done was good, you just weren't given enough time on certain subjects.
>
> *Participant S02/Q04*

Those who travelled by taxi to and from the venue reported how this made it easy to attend sessions, especially for those participants who travelled a long way.

Coherence

Generally, participants said that they understood the intervention and how it works:

> Well I think it was useful, as I say, to reinforce what you're doing . . . and also it was useful to have lunch as well because . . . and it also broke the silence . . .
>
> *Participant S01/Q04*

Perceived effectiveness

Most participants felt that they benefited from participating in the programme, reporting (varying degrees of) weight loss, improved nutrition and increased exercise. Participants felt that being in a group with those in a similar situation was particularly useful. Several participants would have liked more content about physical activity (S04/Q12; S05/Q03):

> Oh, yes, definitely, I've lost quite a bit of weight and I'm in much better shape. Like, I'm healthier because it's taught me do a bit of exercise as well, yeah. Quite helpful. I'm in much better shape as well.
>
> *Participant S06/Q06*

I found it quite useful, there's been some interesting thoughts as well seeing what other people thought of the . . . what we was trying to aim for . . . like-minded and had similar views on medication and stuff as well [as] on gaining weight.

Participant S06/Q02

Yeah . . . I think it needed more talking about the gym like. You know. Like . . . you know to lose weight . . . and, evidence for like towards how you should go to the gym a lot more often.

Participant S04/Q12

Facilitator views of STEPWISE

Sense-making

Staff distinguished STEPWISE from other interventions ('differentiation') in terms of its use of the biopsychosocial (rather than the medical) model, with an autonomy-enabling, rather than a paternalistic, didactic, approach;[122–124] its comparatively structured character (the commonest response); its content, including attention to antipsychotic weight gain; the group and peer-support elements; a greater time commitment; a comparatively short programme duration; its use of boosters and telephone calls; its external management; and its internal delivery – as lifestyle interventions often involve an external referral:

They're encouraged to do our physical checks and look after people's physical health including their weight but . . . it's done more in a medicalised sort of way rather than the way the STEPWISE project offered which is better . . . it's looking at a much more individualised person-centred approach.

Facilitator S06/F05

We don't sort of tell them you can't eat this . . . It's more . . . giving them the opportunity to do what works for them. We are giving them the information for them to work it out for themselves.

Facilitator S04/F02

Only one facilitator, a community development worker, compared STEPWISE unfavourably with another manualised intervention:

[The other intervention] was more thorough in that it went right to the basics starting with food groups, etc. and then moving up, you know, into like portion sizes, about sugars . . . because there's more time you've got more to explain . . . [whereas, with STEPWISE] the background information wasn't there.

Facilitator S03/F05

Facilitators reported understanding what the intervention required of them ('individual specification') and sharing a sense of the aims of STEPWISE with other health professionals ('communal specification'). This understanding was not immediately or always grasped by participants, either because of learning difficulties, cognitive deficit or an expectation of something more didactic involving closer monitoring:

And their functioning is quite different, you know, there's really quite a high-level functioning lady there who sort of understood the thing straight away, and another guy . . . it's very difficult to find out what his understanding actually is. Because he tends to talk in slightly psychotic terms.

Facilitator S05/F02

We do repeat, you know . . . it's a lifestyle choice . . . we're not saying that you've got to ban all bad food . . . they think they're going to go there, get weighed, and they'll go on a diet, we're going to give them a diet sheet. And for some people that would work, and for other people empowering them works . . . sometimes the like peer pressure and going to Weight Watchers and knowing that you know there's some expectation you've lost some weight, because it's been marked down, that works very well for some people but not others.

Facilitator S01/F02

Although most facilitators constructed potential value for STEPWISE ('internalisation'), this was conditional on the trial demonstrating an important difference in participant weight compared with usual care. Anticipated benefits, apart from lifestyle changes and broadly defined well-being, included:

- the opportunity for often isolated individuals to interact, receive peer support, improve their social skills and grow new interests
- an improved understanding of the participant's own situation through *modelling* (intervention function) and self-esteem
- better adherence to antipsychotics in the face of weight gain
- mental health improvements brought on by improvements in physical health
- improving the skillset, confidence and attitude toward physical health of health professionals
- meeting local or national quality improvement targets and
- downstream participant and health-system gains in terms of diabetes mellitus prevention.

Most facilitators agreed that STEPWISE fitted well with the goals of their organisation, although in some trusts they had faced apathy toward referral and scepticism that the intervention would be sustained beyond the end of the study:

> *I think it's for the whole NHS really, because we are spending a lot of money on things like diabetes . . . it's a good opportunity for service users to come together . . . they talk to each other and they share their own views, how they lost the weight, and again like engagement for them to get the social skills . . . when people are quite lonely they can't talk to anybody . . . you can go there you can sit down, you can do a little bit of parkrun [parkrun Ltd, Twickenham UK] in the local park and you can talk to each other. So, it does benefit, it does benefit to the physically, mentally and socially.*
> *Facilitator S03/F04*

> *Quite a few service users get put off continuing to take their medication because of the side effects and this gives them a way to control it so it is not only kind of benefiting their physical health but it will benefit their mental health as well if it's helping them to stay on the medication.*
> *Facilitator S06/F01*

Relational work

The key individuals who drove the intervention forward ('initiation') were different between organisations. Although many facilitators discussed having supportive clinical management, they frequently commented that the trust research departments, rather than clinical managers, were the drivers of implementation. In most trusts, the facilitators presented themselves as ultimately responsible for making STEPWISE happen and one developer flagged the general absence of effective change agents – individuals who influence innovation decisions:[125]

> *I know that people who are key in those sites are people who take part in [research project] meetings . . . they probably do not really see it as their job . . . to be that link with people on the ground . . . you do need senior people, very senior people in the trust to be supportive and to want something to happen . . . at [trust name] . . . the people who sat round that table were on board but practically speaking they were all a bit you know disconnected . . . you have got to have buy-in but you have got to have communication between all levels.*
> *Developer 03*

The facilitators all believed that it was right to deliver a structured lifestyle programme ('legitimation'), reporting that they and most of their colleagues considered that it should be part of their work. One facilitator commented that this was now externally reinforced by the Commissioning for Quality and

Innovation (CQUIN) payments framework, which was incentivising the promotion of physical health in mental health trusts during the study:

> There is nobody who doesn't perceive it as actually a very useful intervention and a useful way of working.
>
> *Facilitator S05/F02*

> Completely compatible really . . . it's very valid . . . It's not reinventing the wheel it's just putting things in place that you need to know to make changes.
>
> *Facilitator S02/F03*

> I think that's [STEPWISE is] definitely something that we haven't been doing. And I think it's something that we should be doing.
>
> *Facilitator S02/F06*

By and large, motivated trust employees put themselves forward for intervention training and delivery ('enrolment'), seeing it as a development opportunity as well as being good for patients; there were some instances in which this was not the case, although the first quotation here is comparably extreme:

> I felt that a colleague was being slightly, mildly bullied into it . . . I had quite a threatening e-mail [after resigning] saying how . . . I was letting down the trust.
>
> *Facilitator S05/F02*

> There were some people who were 'volunteered' and . . . who were less positive but my general feeling when we did the training was that most people had seen STEPWISE and thought 'oh, this looks really interesting, this would be nice thing to do, it fits', you know, 'I'm interested in health promotion'.
>
> *Developer 03*

At some trusts, participants were easily engaged; at others, clinical 'gatekeepers' and patients presented barriers to filling STEPWISE course places. Although the current research context may have aggravated gatekeeping, health professionals in other settings employ tacit and 'informal criteria when selecting individuals' for routine clinical services.[126] Such gatekeeping was also reported to service user co-authors David Shiers and Angela Etherington, in their previous roles as project team members on the National Audit of Schizophrenia:[127]

> We've got more people wanting to do it than we are able to put into our group.
>
> *Facilitator S08/F03*

> A lot of clinicians have said their clients don't like group work or they don't like to leave their home and they've put a lot of barriers in the way of people engaging . . . service users . . . the people who do want to take part are really positive about it . . . it's something that they've been looking for . . . though you do also get some people who say . . . they wouldn't want to talk about it in front of a group of other people, or . . . they don't have the time to kind of stick to it . . . they've already engaged in other activities [gym or nutritionist] . . . the clinician has referred them because they know they're overweight, but actually they don't have concerns themselves . . . a lot of people live quite far away and that's what puts them off.
>
> *Facilitator S06/F01*

> Service users are slightly put off by the thought of engaging in a research project, but I think that there would be a lot more individuals who'd be interested in engaging in STEPWISE if it wasn't part of research, if it was just something that we'd rolled out.
>
> *Facilitator S09/F03*

Although many facilitators continued to support STEPWISE ('activation'), developers noted that there were high levels of facilitator attrition (*Figure 23*) compared with other interventions on the LDC portfolio. Although most of the facilitators had group facilitation experience and relevant experience of the clinical population, there were still concerns among the developers that staff selection was not always well considered:

> *There's no point in training 10 facilitators if they only get to deliver one session . . . obviously at any one time you've only got a certain number of people with capacity and they may not be the right people and, obviously, there were some people who trained and then they went on and got other jobs . . . there was an awful lot of attrition in facilitators. I would have expected quite a bit anyway perhaps not quite as much as we had.*
>
> *Developer 02*

Facilitators saw the availability of transport costs as critical to maintaining participant engagement during the initial four sessions (see *Table 7*). Thereafter, there were problems with keeping participants involved during the follow-up telephone calls (see *Table 9*), because of participants' social commitments and staff annual or sick leave:

> *A lot of times you speak to people about attending the sessions, they say 'well, where's it going to be? And, how am I gonna get there?'. So I think that's been a really good way of keeping people attending the groups, knowing that they can get a taxi and not have to worry about going and getting a bus . . .*
>
> *Facilitator S06/01*

> *It tends to seem to have worked better . . . where they had one person that kind of took ownership of doing all of the calls . . . in most areas it tends to be either one of the facilitators . . . then takes them through their calls and things.*
>
> *Developer D05*

> *No one picks up, you know. And it's how many times really do you try and get through to someone. Erm, but I've always left messages, erm. But I've tried to contact them if I haven't got through. But it's usually about half, we've managed to actually contact.*
>
> *Facilitator S02/F06*
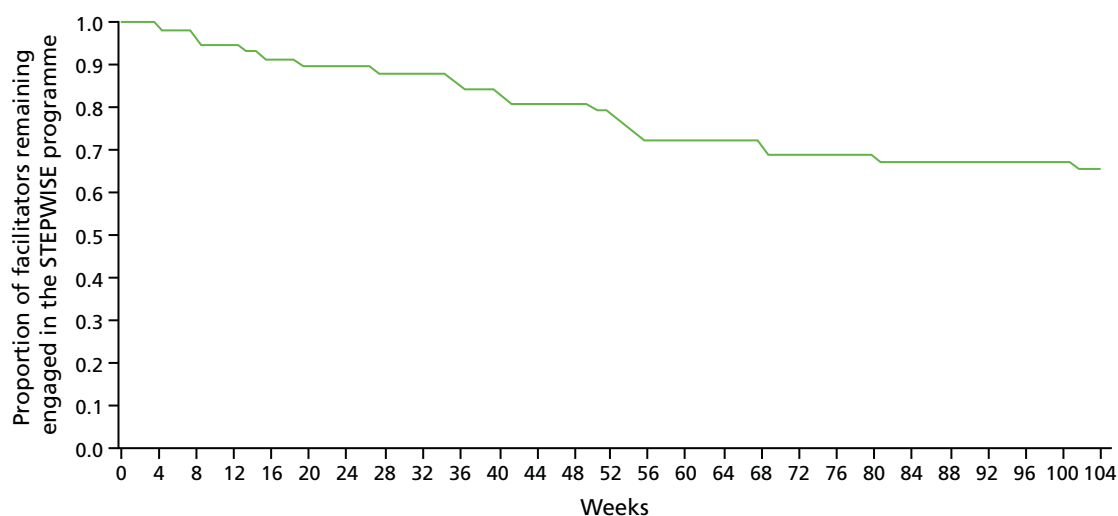
FIGURE 23 Time to facilitator attrition from foundation training (weeks).

It's been quite mixed . . . some of the . . . service users that you'd speak to I think find it really useful . . . to actually reflect back on how the last few weeks have been for them . . . Whereas a couple of people it almost feels like you're pestering them a little bit and they do not have so much of an interest in talking about their diet and exercise levels and it's quite a short conversation that they just say yes everything's fine, no I do not need support with anything else. So it is quite mixed in the response that you get from people.

Facilitator S06/F01

Operational work

Facilitators could perform the tasks required by the intervention ('interactional workability'). They were universally complimentary about the training and printed materials they received, although:

It was a lot to take in just those 3 days initially . . . quite intense.

Facilitator S08/03

Facilitators described how they translated or adapted instructions from the manual to support participants to perform particular tasks. Although most found that delivering their first sessions was tricky, they reported becoming happier with group facilitation over time. Some reflected on the challenges of an autonomy-enabled, rather than a paternalistic, communication style, all believing that they were adapting well to this requirement. However, many facilitators complained about the logistical burden of programme management, in particular the purchase, transport, setting up, taking down and storage of materials, including sandwiches, other foodstuffs and flip charts. Intervention delivery and broader programme/case management could be made more difficult by sick leave or staff attrition. The workability of materials was problematic. For instance, one exercise involved showing pictures of foodstuffs to participants and asking them to discuss how many calories they contained; however, it did not say in the materials and facilitators who were not themselves dietitians did not know the right answer:

Had it not been for her [the administrator] . . . I don't think half of the time I would have turned up with the right stuff. And it would have took me a full day. It's only because she had everything organised . . . on a Wednesday morning she was getting me the stuff together. Erm, now some of the stuff was out of date. That meant that we then had to go to the shops and go and buy replacements, which we're still waiting for the money, we paid for it out of our own pockets. And er I know £10, £13, doesn't seem like a lot but erm when you're waiting 4 months for it . . .

Facilitator S01/F02

Facilitators sometimes alluded to the repetitive nature of aspects of the intervention causing problems with some participants. They mentioned the problems of dealing with a client group in whom concentration could be poor. Sometimes, one facilitator had to break off discreetly to support participants who were struggling because of learning difficulties or symptoms. Small groups (≈4 participants) seemed to allow enough time for the delivery of course content and for participants to come up with their own solutions, whereas larger groups often felt rushed. One facilitator found that supporting participants to complete the action-planning task was the most difficult part, but that retaining flip chart notes from across the sessions helped to prompt and persuade participants to engage with the task. The timing of content delivery during the sessions, and completing within the allotted time, was a source of anxiety for facilitators – given the need for a smooth conclusion by the time taxis arrived:

It was a booster session I did recently, and erm this client said, halfway through she like put her hands, er her head on table, and she said 'I'm going to have to go . . . I've lost the will, you know. Because everything's been said over and over' she said, 'and I've just had enough.' And I thought 'well that's how I were feeling actually'.

Facilitator S01/F02

In general, facilitators maintained trust in each other's work and expertise during the delivery of STEPWISE ('relational integration'). In particular, they described being reliant on each other to share the logistical burden and provide cover when things went wrong in session delivery. They felt that a wide range of other people would need to be involved in one way or another, aside from the facilitators and the senior management, to ensure the smooth running of STEPWISE:

> *GPs . . . community teams . . . nurses, social workers . . . care co-ordinators, medics involved in the community mental health teams, so they can, you know, have an overview of you know the blood results . . . and signpost people that might be having any issues with physical health . . . someone to arrange taxis . . . an admin person . . . people's carers or support network . . .*
>
> *Facilitator S01/F04*

Two types of comments indicated that some facilitators felt that others might not be qualified to deliver the intervention; some felt that more specialist nutritional training should be required and one felt that overweight facilitators should not be delivering the course, although other facilitators had talked about being overweight themselves:

> *I'd say it's the people who haven't got the nutrition background that I worry about, not necessarily the . . . or not feeling competent, or not knowing that they're not competent.*
>
> *Facilitator S02/F06*

> *[Facilitators] are like a role model, you know what I mean? . . . if I am overweight . . . they will think, oh my goodness, he or she is overweight and they are talking to me about this programme like to lose the weight, and he hasn't or she has not lost any weight at all.*
>
> *Facilitator S03/F04*

Otherwise, facilitators agreed that the work of delivering STEPWISE was appropriately allocated ('skill set compatibility').

Every facilitator mentioned resource scarcity, with even paper and whiteboards at a premium. The venues provided for sessions were generally adequate, but the storage of materials was often a problem. Programme or case management and tasks, including preparation/documentation of sessions and writing up telephone support logs, were very time-consuming and added pressure to the facilitator's job: facilitators at almost every trust said that the time required had been radically underestimated in what was allocated to them. More than one facilitator had to stop delivering STEPWISE because its delivery was affecting their clinical work and some commented that the intervention was fragile in the face of clinical emergencies and staff sickness, maternity leave and turnover.

Some facilitators implied that the intervention was not adequately supported by the host NHS trusts ('contextual integration'); although the senior management supported the principle of addressing physical health, the resources were not forthcoming. Backfilling clinical time involved was sometimes a matter of immediate staff availability rather than financial constraints or management motivation. Facilitators at several trusts, said that, with inadequate backfill, clinical colleagues had missed their presence. Things were reported to be working better in trusts, which had clear and meaningful buy-in from the senior management and when CQUIN incentivised the delivery of something like STEPWISE (see *Relational work*):

> *[My time] didn't get backfilled . . . I did actually get some . . . negativity . . . from some of my colleagues. Because, well, to quote one person, I was taking the piss because . . . I'd put a lot of this time, blanked it out in my diary . . . [STEPWISE has been] ignored since we've done the training . . . I think the system has . . . failed the programme a little bit . . . if it's going to be successful then we've got to have resources for it.*
>
> *Facilitator S01/F02*

It's just a case of senior management being completely blind . . . anything above team leader level . . . They all go, 'yes it's lovely', but then . . . do not then provide us with the resources to be able to do it . . . there isn't a system to allow members of staff to do something like this . . . They say there is, but there isn't . . . if there is a system it is flawed and broken.

Facilitator S05/F02

It's a big piece of work when you're full-time somewhere else, and they would say well we've got money to backfill but there's no staff to backfill.

S09/F03

Within this particular trust, one of the deputy directors had been involved right from the start and he was very keen for it to happen so it's been sort of disseminated downwards from there . . .

Facilitator S03/F05

Appraisal work

The extent to which facilitators accessed information about the effects of the intervention ('systematisation') was limited. None was routinely accessing information on participant weight and this would have been possible only at a minority of trusts where weighing was routine and performed at regular intervals. Instead, most facilitators reported participant anecdotes involving the adoption of desirable behaviours by participants and (in terms of cooking) their carers:

No one seems to be taking weight! [laughs] We're just getting, I'm not gathering data on individual clients . . . we do not even have an ongoing way of monitoring weight now. I think the trust would like it, but we keep telling them there is no way of actually monitoring people's physical health on the system that we have got . . . you have to go through a hundred different things and write them all down separately, and then you can draw a graph . . . I think the trust is willing, and would like it, but they just do not know, they are just not willing to put the money and the investment into the IT [information technology] things.

Facilitator S05/F02

I am not sure whether when they leave our session whether they follow the advice . . . [one] service user has been telling to her mother not to add too much oil to curry and things like that . . . so there has been some insight there.

Facilitator S03/F04

I had one person that said 'I was eating takeaways nearly every single night and I've stopped doing that now'.

Facilitator 03/F05

Few facilitators reported having the opportunity to assess the worth of the intervention together ('communal appraisal'); however, when this did happen, the conclusion was usually positive:

The facilitators we'd spoke between ourselves, but there wasn't anywhere where you could go really and feed back to someone.

Facilitator S01/F02

I did a talk at a . . . bite-sized physical health training game . . . about STEPWISE and it was a very positive response, and generated a lot of referrals for the group.

Facilitator S06/F04

Well I've actually had people come up who've heard about it. Who were talking to people that go to the clubs or clinics. And they've spoken to some people who have attended it and they are keen to know whether there are going to be other groups and things.

Facilitator S08/F03

Although they stressed that their final appraisal was contingent on the outcome of the RCT, facilitators individually assessed the intervention as worthwhile ('individual appraisal'), with only two exceptions. The benefits for participants were expressed as:

- having the opportunity to think through their lifestyle
- having the opportunity to meet other people and openly discuss antipsychotic-related weight gain
- maintaining self-esteem in the face of weight gain.

Some facilitators thought that these benefits would have positive effects on mental health. The benefits for professionals included:

- raising the profile of physical health and the poverty of current services
- new communication skills or knowledge they had learned that had applicability beyond STEPWISE, which, in turn would make them more confident in giving lifestyle advice.

Criticisms of STEPWISE included that elements were repetitive or patronising, that it lacked incentives for behaviour change, that it was not underpinned by adequate dietary or nutritional knowledge and that behaviour change momentum would not continue without group support:

> *One of the patients was saying, it's all good when we're doing it together, but I live alone and I find it difficult to cook just for myself. It would be good if we could you know once in a while meet again and you know, make a meal for, for each other, altogether sort of thing. So yeah, er, the philosophy is good, it's whether people will be consistent and continue it afterwards . . .*
>
> *Facilitator S07/F05*

Many participants said that they would be modifying their work in response to their appraisal of STEPWISE. In particular, they valued the client-centred, autonomy-enabled communication style, which they had learned in training, and some planned to use that style and to insert more structure into other clinical encounters as a result of their experience. Some identified other populations, not targeted by the RCT – such as people with borderline personality disorder – who could benefit from a STEPWISE programme. On the other hand, some facilitators thought that, if STEPWISE was sustained, it would have to be modified, in particular to take account of its current resource intensity, with materials and lunches in particular jeopardy:

> *It's actually made me think a little bit more about you know the style that I deliver my groups in for other service users.*
>
> *Facilitator S02/F03*

> *I know a number of people that would really benefit from STEPWISE but they can't take part because . . . they don't meet the criteria.*
>
> *Facilitator S09/F03*

> *If it works, I wouldn't imagine that we're going to be running these sessions, it's going to become part of like the working practice for everybody. We won't be giving out free gifts and you know weight scales and books and everything else. It will just be the programme as it is, as an ongoing thing. You know part of people's care plan.*
>
> *Facilitator S01/F02*

> *Obviously it's potentially quite expensive to run, that's the only thing, because the lunches and support tools, so all those things would need to be considered, uhm . . . whether there were potential long-term benefits because cost is a huge implication for the trust.*
>
> *Facilitator S08/F05*

Summary

The findings are summarised in *Figure 24*. STEPWISE made sense to those who delivered it. They understood its objectives and believed that it could be worthwhile. At most trusts, change agents in senior management did not drive the intervention forward and, although facilitators felt that the intervention was the right thing to do and they became involved, competing clinical caseload demands and other factors resulted in high staff attrition. Facilitators understood how to deliver the intervention, gaining confidence with practice, maintaining trust in each other and drawing on their expertise. However, programme management was under-resourced and facilitators doubted the long-term commitment of senior management to what they perceived as a resource-intensive intervention. In no trust were facilitators accessing data on weight to understand the effects of STEPWISE; instead, they relied on ad hoc participant self-reported accounts of the enactment of cognitive and behavioural skills. Facilitators rarely collectively appraised STEPWISE; individual appraisals were generally positive. Many reported modifying their own practice based on STEPWISE training and thought that STEPWISE was applicable to other mental health populations, with some anticipating modifying STEPWISE, because it would have to be less resource intensive to be sustainable.

Implementation process

Programme theory and logic model

The programme theory, elaborated in the logic model (see *Figure 5*), is described as follows. For the STEPWISE programme to work, certain *resources* need to be in place, including the facilitator training and quality assurance infrastructure and resource allocated by CMHT management for programme delivery. This being the case, certain *activities* can be delivered; LDC would train and quality assure trainers, who would, in turn, train and quality assure STEPWISE facilitators. Clinical gatekeepers would refer participants. Facilitators and local co-ordinators would perform case management and wider programme management functions. *The immediate outcomes* would be that the quality of every level of training is maintained, STEPWISE courses are delivered and eligible patients are referred to and attend the group. Through the participants' receipt of the course content, the *intermediate outcomes* measured by the trial were brought about.

Sense-making

Facilitators:
- Distinguish STEPWISE from other services
- Collectively agree on its aims and objectives
- Individually understand what the programme requires of them
- Construct potential value for STEPWISE conditional on RCT results

Participation

Facilitators:
- Did not generally find that key individuals drove implementation
- Bought into STEPWISE
- Enrolled themselves and participants
- Dropped out in large numbers

Action

Facilitators:
- Translated manuals into action
- Occasional concern that some facilitators had insufficient nutritional knowledge
- Believed that they had the right skills to deliver STEPWISE
- Found that delivery was under-resourced and sometimes doubted management commitment

Monitoring

Facilitators:
- Could not access information about the STEPWISE intervention's effects
- Did not collectively assess its worth
- Were mostly positive about its effects on them and their workplace
- Anticipated reconfiguring STEPWISE, and sometimes their practice

FIGURE 24 Summary of the qualitative findings understood through the normalisation process theory.

Resources

Programme infrastructure/trainers/mentors/managers

During the trial, LDC staff fulfilled these roles (excepting management), as they currently do for active services such as DESMOND and the Let's Prevent Type 2 Diabetes programme (see *Chapter 1*, *The Leicester Diabetes Centre structured education approach*). Interviewee D02 highlighted that, should the STEPWISE intervention be sustained and commissioned more widely, a permanent infrastructure would be required. At the top end would be a steering group with a national director, educationalists, consultant clinical psychologists and quality assurance experts ($n \approx 6$ in other programmes). Below the steering group would be a training and assessing team ($n \approx 6$ in other programmes). At each site, there would be a STEPWISE lead linking with the steering group; if the lead does not have easy access to senior management, a separate champion might be required to ensure adequate resourcing (see *Facilitator views*, *Operational work*).

Facilitator training course and venue

During interviews with LDC staff and facilitators, no systemic problems were identified with resources for training, details of which are in *Table 35*. Course materials were well regarded by facilitators (see *Facilitator views*, *Operational work*).

TABLE 35 Facilitator training dates and costs

Facilitator training/resources	*n*	Cost (£)	Details
Original facilitator training	48[a]	4413.70	3–5 March and 10 June 2015 (Sheffield); 21–23 April and 24 June 2015 (Southampton); 28–30 April and 7 July 2015 (Exeter). Three sites trained six (rather than four) staff
Booster training day (original)	35	3151.51	Not all facilitators in the original training completed the booster training day (dates above)
Additional (full) training	7	1932.23	Four sites identified seven staff for training: 3–5 November 2015 (Leicester)
Additional booster training	5	554.45	Cost of staff attending alternative training dates (booster session content only). One out of five did not attend
Additional booster and support contact	5	1250.00	Five facilitators from three sites were trained: 6 and 7 June 2016 (Sheffield)
Core teaching kit and supporting kit	–	17,395.34	
Training subtotal		28,697.23	
Delivery resources	**n**	***Cost (£)***	
Patient handbooks	–	3908.32	
Lunch		4410	Costs based on a price per head of £3, assuming that seven participants attended all seven group sessions × 3 waves ($n = 21$ intervention participants) at each site ($n = 10$). Paid directly to the University of Leicester by NHS trusts
Resources subtotal		8318.32	
NHS staff costs		***Cost (£)***	***Assumptions/notes***
Facilitator/s time to deliver courses	40	46,980.00	Based on 4 × 0.05 WTE Agenda for Change band 7 (point 30) for 24 months
Administrator time to support delivery	10	173,412.00	Based on 0.1 WTE Agenda for Change band 3 (point 9) for 24 months. Activity: room bookings, pre-course material, booking taxis, processing expense claims and collating attendance logs
Staff subtotal		220,392.00	
Total		257,407.55	

WTE, whole-time equivalent.
a Not all facilitators in the original training completed the booster training day.

Health professionals motivated to become facilitators

Motivation was generally high in interviewees (see *Facilitator views*, *Relational work*) and, although facilitators had a wide range of exposure to group facilitation (see *Table 5*), the LDC team felt that appropriate individuals came forward. However, quantitative data highlighted problems with staff attrition from facilitation (see *Figure 23*).

Appropriately resourced co-ordinator

Interviews with facilitators and the LDC team indicated a lack of clarity about the roles of the co-ordinator and/or under-resourcing at some trusts:

> *There were sites where you had a very proactive co-ordinator . . . helping the facilitator to make sure that everything was there and they had everything they needed on the day and the taxis were booked and you know the logistics of running it went well . . . I got the impression in some other places that actually that wasn't quite the case . . . it was very much left to them [facilitators].*
>
> *Developer D03*

Bought-in trust chief executives and gatekeepers

Senior management buy-in was often good, but sometimes did not translate into appropriate resourcing (see *Facilitator views*, *Operational work*). Similarly, gatekeepers referred patients well at some trusts and less well at others (see *Facilitator views*, *Relational work*). The budget for taxis was always available and deemed to be very necessary (*Context*, *Activities and participation*).

STEPWISE course materials

There were difficulties in arranging the storage of course materials (S01/F04). The necessary budget for consumables [paper, Blu Tack (Bostik, Paris, France), whiteboard] required for the course was sometimes not forthcoming (S01/F04). The necessity for facilitators to buy materials, in the absence of a properly funded co-ordinator, was problematic (see *Facilitator views*, *Operational work*).

People with schizophrenia motivated to attend

The study screened 1223 people for eligibility, of whom 800 did not participate. A total of 406 out of the 800 people excluded actively expressed a lack of interest or declined consent.

Activities

Mentors assessing the competency of trainers

As the training in the trial was conducted by DESMOND trainers, who are themselves mentors, this activity was not conducted.

Training of facilitators

Forty-nine facilitators were fully trained in 8 months by seven trainers, with additional booster/support contact training provided to a further five staff (see *Table 35*). Training was well regarded by facilitators (see *Facilitator views*, *Operational work*). The STEPWISE programme employed generic strategies[24] to ensure intervention fidelity through training; these included standardised training and accommodating provider differences (see *Table 6*). LDC does not assess provider skill acquisition at baseline or attempt to minimise provider skills 'drift';[24] rather, the DESMOND programme expect, gradual skill acquisition through ongoing observation, feedback and self-reflection – a process not simulated in the STEPWISE trial, because of the short-term study-specific commitment to the intervention, and the burden of additional procedures:

> *We would never, ever say because we train people for 2 days or 3 days that that means they are absolutely fantastic . . . it's only the beginning of the journey . . . the process by which people get accredited is that, within 6 months after training, people get a mentorship visit from an experienced trainer/assessor . . . and they'll sit and they'll observe and they'll use tools that are available to the educators themselves . . . and they will give some mentorship . . . the person does an action plan . . .*

and probably within the next 6 months they'll have an accreditation visit where they will be observed delivering 50% of the programme . . . and, as a result of that, they'll either be accredited or they'll have to do a little bit more work. Most people get accredited within 18 months if they follow that process.

Developer D02

The LDC's approach to minimising skills drift is to encourage facilitators:

To form a community of interest in their organisation, support each other, make links with neighbouring organisations . . . the reason that we don't do any more competency [assessment] is because organisations won't pay for it and . . . they'd never get the time released.

Developer D02

Programme management

The work taken to realise the client interactions was described universally as greater than anticipated. Although facilitators at many trusts rose to the challenge, the experience of programme management had distressed or overfaced some facilitators. Scheduling of courses was reported to be chaotic in some trusts, with delays and cancellations observed and facilitators being obliged to travel long distances to deliver courses in multisite trusts. Facilitators sometimes found it difficult to protect time to plan, to deliver the intervention uninterrupted by client emergencies associated with their usual clinical role or to debrief (see *Facilitator views*, *Operational work*). Under-resourcing of local co-ordinators or a lack of clarity about their role meant that facilitators spent undue time preparing refreshments, booking taxis, transporting or storing materials, and so on (D01):

I think they underestimated the amount of time doing these programmes . . . you have got to spend a lot of time reading through the material . . . And because the, the groups are run off site from where I work, I've got to get there, set the groups up . . . it is a big investment in time. And it does sort of create strains a lot of days . . .

Facilitator S02/F02

But for me there was a lot of work behind the scenes . . . obviously my caseload is my paramount priority so if there's any kind of downtime, STEPWISE would slip into that . . . I've had to do some at home . . .

Facilitator S02/F03

It's the calls that . . . take quite a lot of time. Because not everybody picks up the phone the first time, you need to call back . . . the groups are quite easy to, to manage, with workload, but I think the calls are definitely more difficult to fit in.

Facilitator S02/F06

It takes planning . . . the 4 weeks [foundation course] . . . it was almost impossible. Because I was suddenly having to put 5 days of work into 4 days of work. You know, but our caseload did not go down, I still had the same number of ward rounds to attend, same number of clients to see each week . . . I was told there would be backfill, I was then . . . told that the backfill would not actually cover the hours that I was actually working it . . . there was no acknowledgement of the fact that every e-mail takes 5, 10, 15 minutes to reply to, that there were extra meetings . . . they wanted us to buy our own tickets for . . . 3 days travel down [to training] . . . We absolutely refused, it was a nightmare getting those tickets . . . I cannot remember how many hours . . . I'd put into it. But it's a lot more than other people thought . . . I think they thought . . . that delivering the session would be 3 hours of our worktime. No! It's a day of our work time . . . far more than just 4 hours a week. Because . . . it was 2–3 hours of preparing each session at home.

Facilitator S05/F02

Gatekeepers actively refer people

Gatekeepers were rarely reported to be a barrier to participant recruitment (*Facilitator views*, *Relational work*). Health professionals encouraged involvement with STEPWISE, as they recognised that weight management was a huge problem for the client group.

Case management

Many facilitators described having an existing psychiatric caseload 'over multiple wards in multiple locations' (facilitator S02/F03). Inadequate resourcing and lack of protected time (see *Facilitator views*, *Operational work* and *Implementation process*, *Activities*) made individual-level, STEPWISE-specific participant interaction difficult to schedule and complete. Scheduling telephone calls could be difficult because of staff availability and participant commitment, as could arranging cover for staff leave to avoid missing calls that were due. Telephone calls were often described as resource intensive, owing to the number of calls that had to be made before contact was established and, for this reason, the workload of case management was easier in small groups. Facilitators recalled providing additional support to cognitively challenged participants who were struggling with content in the sessions. Many also felt that they needed to be responsive to non-weight management concerns brought up during booster sessions and one-to-one calls, which made calls longer:

> *I felt it would have been better to have people . . . specifically doing that role . . . being taken away for half a day . . . for the period for when you're doing telephone calls . . . having a block of time not at your own desk, at another desk 'cause . . . if I'm on this call . . . for STEPWISE I could easily get interrupted because . . . we respond quickly to our patients and somebody might come in and say, 'OK I need you now!' You know and then you're having to stop.*
>
> *Facilitator S01/F04*

> *Patients also can be funny with a strange voice or someone they don't know. I've had that problem with follow ups. The patients wouldn't answer, or when they heard somebody's voice sometimes they'd just put the phone down. And then I would then phone them . . . and then explain that my colleague would be doing the follow up, and he is trying to get in touch. There was one participant . . . she said yeah I haven't been feeling well so I haven't been answering my phone.*
>
> *Facilitator S07/F05*

Immediate outcomes

Eligible people invited to attend STEPWISE 'recruitment' and 'reach'

Recruitment to STEPWISE was somewhat artificial, owing to the trial-specific consent and randomisation procedures. Recruitment to the STEPWISE trial and programme was reliant, primarily, on referral from direct care teams. A script was circulated for use by clinical team members in conversations with patients about recruitment, in order to provide a consistent message. Site PIs talked to clinical teams about the study and intervention around 1 month before recruitment commenced. Posters, including eligibility criteria, along with short information leaflets co-produced with patients, were displayed by clinical teams in reception areas. Given the engagement of gatekeepers and adequate co-ordination, it seems unlikely that recruitment in real-world circumstances would be problematic.

Estimates on the number of potential participants varied significantly between NHS trusts, partly because of different methods and definitions of 'first episode psychosis'; for example, these ranged from 1233 (Sheffield; 2 June 2017), 2420 (Bradford; 28 March 2014) to 12,968 (Sussex; 11 April 2014). Target versus actual recruitment at these sites was 40 out of 36, 50 out of 45 and 42 out of 35, respectively. Work and family commitments affected the attendance at (or reach[61] of) STEPWISE. Qualitative work identified two participants who were unable to make certain sessions because of child care responsibilities. Care providers rescheduled the start time of foundation sessions to accommodate participant child care responsibilities (S04/Q06) and for when booster sessions fell on a school holiday (S04/Q02). Information from screening logs showed that 11 people gave employment commitments as the reason for them being unable to

participate. Many participants said that they were unable to attend, but did not provide specific reasons; however, one interviewed participant (S06/Q01) was able to attend STEPWISE because it fell on a non-work day.

Foundation, booster and telephone support calls: 'dose delivered'

Foundation sessions and most booster sessions were delivered as planned. Not all sessions were delivered by two trained facilitators, and, on one occasion, a (7-month) booster session was not delivered. Further non-compliance was recorded as a result of only one facilitator delivering the sessions (see *Chapter 4, Course delivery and protocol non-compliance*). When this occurred, most centres provided the facilitator with an (untrained) member of staff to provide support in the sessions.

Sessions delivered in line with the STEPWISE philosophy: 'fidelity'

When we interviewed LDC staff about their observations and read their notes, they generally indicated that facilitators had achieved a reasonable initial level of fidelity with the STEPWISE philosophy, although there was often room for improvement. For instance, most LDC interviewees identified that facilitators would give their own examples of a phenomenon, rather than allowing participants to remember and voice their own experiences. Equally, LDC staff felt that participants were sometimes not given sufficient thinking time to answer a question, which was particularly important given the cognitive challenges some participants face (see *Body functions*) and that aspects of the programme, such as action-planning, were not given adequate time:

> *I think overall with the ones I observed, they did overall well with the talking time, erm but I did observe a couple of times in terms of asking questions to the group they weren't really giving them time to answer back, in terms of kinda letting them think about the answers.*
>
> *Developer D01*

> *It was done in a more didactic telling way than what we'd hoped . . . there were people who went off-piste . . . and added bits . . . there was one place where somebody . . . started doing CBT . . . because they'd been on the [CBT] course recently . . . it took it huge amount of time and there wasn't enough time left for the, for the other elements.*
>
> *Developer D03*

The facilitators were very conscious of – and expressed mixed views on – how structured the intervention was, with some acknowledging departures from the course:

> *I think the level of structure has probably been the most structured that I've come across [in a manualised course].*
>
> *Facilitator S08/F05*

> *I'll be quite honest and say we haven't been quite so structured as the book will give it. And we sort of twisted things slightly in the way we might use some of the supporting tools.*
>
> *Facilitator S08/F03*

> *CPNs [community psychiatric nurses] tend to work very individually . . . tend to be very autonomous workers, and it was challenging . . . to follow specific guides and you know . . . leave gaps and things.*
>
> *Facilitator S05/F02*

Table 36 and *Figure 25* show that the overall mean (SD) for the percentage of facilitator talk time (DOT scores) across four sections of sessions ('Sharing stories', 'Topic a', 'Topic b' and 'Next steps') was 47.6% (12.3%). Mean (SD) scores ranged from 36.8% (6.4%) in Devon to 63.2% (9.4%) in Cornwall. Although the DOT scores provide indicators of the level of competence of the facilitators, precise scores that would be considered acceptable cannot be determined by the trial, as a large sample would be needed and linked to outcomes.

TABLE 36 Fidelity ratings for session sections observed by centre

| Centre	Group sessions observed (*n*)	'DOT' scored session sections (*n*)	% of facilitator talk time		Facilitator behaviour scores, session sections (*n*)	% positive ('left')		% negative ('right')	
			Mean (SD)	Median (range)		Mean (SD)	Median (range)	Mean (SD)	Median (range)
Bradford	2	8	46.6 (6.8)	45.5 (39.0–57.0)	8	46.4 (12.2)	47.1 (25.7–62.9)	26.8 (8.2)	28.6 (14.3–37.1)
Cornwall	2	8	63.2 (9.4)	63.8 (50.0–78.0)	8	31.8 (13.2)	34.3 (14.3–54.3)	38.9 (13.9)	35.7 (20.0–62.9)
Devon	2	7	36.8 (6.4)	37.0 (28.0–44.0)	7	59.6 (6.7)	57.1 (54.3–71.4)	3.7 (2.2)	2.9 (0–5.7)
Leeds and York	6	22	50.0 (13.1)	52.5 (27.0–78.4)	24	57.5 (10.2)	57.1 (37.1–77.1)	21.0 (11.5)	20.0 (2.9–40.0)
Manchester	2	8	41.6 (8.3)	45.5 (29.0–50.0)	8	64.6 (17.7)	65.7 (42.9–85.7)	7.1 (11.7)	0.0 (0–28.6)
Sheffield	1	4	42.5 (5.2)	42.3 (36.4–48.8)	4	63.6 (16.9)	65.7 (42.9–80.0)	20.7 (15.5)	15.7 (8.6–42.9)
Somerset	1	4	44.0 (8.8)	45.5 (32.0–53.0)	4	64.3 (6.8)	61.4 (60.0–74.3)	15.0 (4.9)	15.7 (8.6–20.0)
Southern Health	2	8	50.8 (8.2)	49.0 (41.0–66.0)	8	45.4 (11.1)	45.7 (28.6–62.9)	41.4 (14.6)	40.0 (14.3–60.0)
South London	6	23	49.3 (13.0)	48.1 (25.0–75.0)	23	48.1 (14.2)	45.7 (20.0–71.4)	31.4 (14.5)	28.6 (11.4–65.7)
Sussex	6	24	44.5 (12.9)	44.5 (22.0–65.0)	23	61.5 (12.2)	57.1 (34.3–85.7)	20.7 (12.4)	20.0 (0–40.0)
Overall	30	116	47.6 (12.3)	47.4 (22.0–78.4)	117	54.1 (15.0)	54.3 (14.3–85.7)	23.8 (15.4)	22.9 (0–65.7)
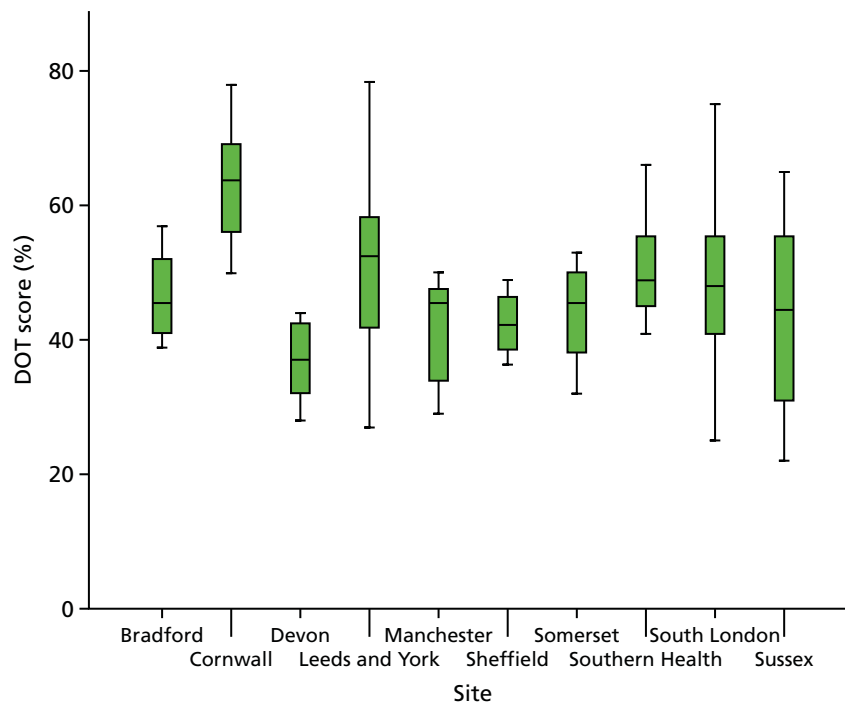
FIGURE 25 Box plot for percentage of facilitator talk time (DOT scores) across sites.

Facilitator behaviour was also assessed by direct observation and categorised as 'positive', reflecting a facilitative approach, and 'negative', reflecting more didactic teaching. Positive behaviour was observed for a mean (SD) of 54.1% (14.97%) of the time, with a range across centres of between 31.8% (13.18%) in Cornwall and 64.6% (17.67%) in Manchester (see *Table 36* and *Figure 25*). Conversely, the mean (SD) time of negative behaviours observed was 23.8% (15.45), with a range between centres of 3.7% (2.16) in Devon and 41.4% (14.57) in Southern Health.

The STEPWISE intervention contained explicit strategies for assuring the fidelity of delivery in terms of reducing differences within the treatment and ensuring adherence to the protocol (see *Table 6*). It did not contain any explicit strategy for controlling provider differences; findings from the session feedback, interviews and observations were not fed back to facilitators during the study. Serious contamination seems unlikely, although facilitators from a number of trusts admitted lifting content or using the communication style that they had learned in STEPWISE training in interactions with other patients. When asked, they did not believe that this might have involved control arm participants, with one exception:

> *I care co-ordinate one of them . . . we've always discussed actually longer term what she needs to be doing to lose weight. To get motivation and things like that. So it just, that's in use. I tried very hard not to bring STEPWISE stuff into it because honestly I don't want to impact on her control group but in conversations that I've with her for a number of years.*
>
> *Facilitator S08/F03*

Attendance and 'receipt' of behaviour change content ('dose received')

Participants attended a median of four (0–4) group foundation sessions and two (0–3) booster sessions. Forty-seven out of 172 participants randomised to STEPWISE attended all seven group sessions, 96 attended all foundation sessions and 61 attended all three booster sessions. One hundred and sixty-nine participants (81.6%) had at least one support contact. Most (75.6%) were by telephone and 167 (81.0%) had at least one telephone contact. Participants received, on average, 15 contacts and the average time per contact was 5.2 minutes. Fewer participants, 68 (32.9%), had at least one face-to-face contact with an average of three contacts and an average time of 59.4 minutes per contact. Furthermore, 105 participants (50.7%) had at least one mail contact, with the average number being five, whereas 24 (11.6%) had at least one contact by e-mail.

Strategies to ensure 'receipt' of the intervention, in terms of ensuring participant comprehension or using cognitive and behavioural skills, were less robust than those to ensure delivery (see *Table 6*), with the intervention prioritising client autonomy. Some of the LDC team and a minority of facilitators acknowledged this as a potential problem, owing to the cognitive function of some of the participants (see *Context*, *Body functions*):

> *Sometimes it wasn't explored to check understanding . . . for example when people were asked to do their plans . . . I would want to say with somebody, 'summarise what key message you've taken away from that session', and I didn't see a lot of that . . . I don't think we cover it in training so again, it's something that could be emphasised more.*
>
> *Developer D07*

> *Their functioning is quite different, you know, there's . . . [a] lady there who understood the thing straight away, and another guy who . . . I think he does have an understanding but it's very difficult to find out what his understanding actually is. Because he tends to talk in slightly psychotic terms and . . . very concrete thinking.*
>
> *Facilitator S05/F02*

Triangulation

Convergence assessment
Table 37 shows how the quantitative and qualitative findings converge. There was agreement on three components, partial agreement on two, silence on six (all expected areas were amenable to only one form of assessment), and dissonance on seven. Some areas of dissonance indicated that data were being collected on quite different aspects of the construct, for instance the amount of resource committed versus how the result was valued. In other areas, qualitative research revealed nuances, for instance, although resource for co-ordination was allocated, it was insufficient.

Completeness assessment
The quantitative research contributed information to 14 out of 18 logic model components, whereas the qualitative components contributed to 16. This was expected: some components were not amenable to investigation in quantitative terms.

Brief summary
The numbers relate to rows in *Table 37*. The study was not run in naturalistic conditions, meaning that national (1, 11) and local (6) infrastructure for quality assurance was not in place. Training resources were adequate (2). Most health professionals were motivated, but neither co-ordination resource nor senior leadership were adequate at some trusts (3). The STEPWISE course materials were popular with participants; professionals doubted their sustainability (4). When offered the STEPWISE trial, half of the people with schizophrenia were motivated to participate (5).

Training and fidelity assessments were conducted (7). Facilitators often felt that programme management (8) and case management (10) were under-resourced and, as a result, stressful. There was some evidence of clinical gatekeepers barring entry to eligible people, but we do not think that this was widespread (9).

TABLE 37 Triangulation table

Logic model construct	Data Quantitative	Qualitative	Convergence code
Resources (see the Resources section, except where stated otherwise)			

1 STEPWISE programme
    • Infrastructure
    • Trainers
    • Their mentors/managers
	Costs of infrastructure and mentors/managers not included in this experiment	Seven LDC mentors/managers played the role of trainers for this experiment. Infrastructure to be established if the trial is successful and the market allows	**Agreement.** This research does not provide evidence of effective infrastructure to sustain the STEPWISE programme

2 Training course materials and venue	Training costs: £2868 for 10 centres	Course materials are universally popular resources (see *Relational work*). Limited availability but good acceptability of venues	**Dissonance.** The meaning of items coded to this construct are different. Costs were committed; they were adequate and deployed successfully
3 Health professionals motivated to become STEPWISE facilitators (ideally experienced in group facilitation) and an appropriately resourced co-ordinator and a bought-in NHS trust chief executive and gatekeepers	Group facilitation experience was variable; co-ordinator excess treatment costs were £1734 per centre; facilitator excess treatment costs were £468 per centre (10 centres) for three courses of six to eight participants	Motivation generally good, with some exceptions (see *Relational work*). Co-ordinators assumed to be appropriately resourced – although administration load on facilitators was a common complaint (see *Operational work*). A minority of those interviewees did not believe that people of sufficient seniority drove the intervention forward (see *Relational work*)	**Dissonance.** The meaning of items coded to this construct are different. Costs were committed. In some cases, it was claimed that both monetary and wider organisational commitment was inadequate
4 STEPWISE course materials: venue, leaflets, patient handbook, refreshment, travel costs	Excess treatment costs for course materials: £832 per centre (10 centres); venue costs hidden in crude costs	Subsidised travel, course materials and refreshments were popular with participants (see *Course delivery and protocol non-compliance*), but facilitators sometimes doubted their sustainability (see *Predictors of weight change*)	**Dissonance.** The meaning of items coded to this construct are different. Resource was committed, popular with patients, but sometimes seen as unsustainable by professionals
5 People with schizophrenia were motivated to attend the course	The study screened 1223 people, of whom 800 did not participate. A total of 406 out of 800 exclusions expressed a lack of interest or declined consent	–	**Silence.** No qualitative data about the motivation of the wider population

TABLE 37 Triangulation table (*continued*)

		Data		
Logic model construct		**Quantitative**	**Qualitative**	**Convergence code**
Activities (see the Activities section, except where stated otherwise)				
6	STEPWISE programme mentors frequently assess the competency of trainers	–	The research project did not incorporate a system of mentorship located within trusts	**Silence.** Quantitative data did not speak to mentorship arrangements
7	Trainers train and periodically assess the fidelity of NHS trust-based group facilitators	Three facilitator training courses ran from March to July 2015; 48 facilitators attended core training, of whom 42 attended booster/ support training. November 2015 to June 2016, seven staff attended full training; five were trained in booster/support contact only. Ten per cent of group sessions were observed using the DOT and facilitator behaviours checklist	LDC interviews confirmed training and fidelity assessment observations	**Agreement.** Both data types confirmed that action was completed
8	Programme management (including the identification of staff, booking rooms)	–	Programme management felt under-resourced and stressful for many facilitators (see *Operational work*)	**Silence.** Quantitative data did not speak to programme management
9	Gatekeepers actively refer people	Screening CRFs captured three incidents in which the care co-ordinator did not give permission to contact potentially eligible candidates, and two in which an assistant practitioner referred a candidate and the care co-ordinator blocked contact	Facilitators confirmed that gatekeepers sometimes presented barriers to participation (see *Relational work*)	**Agreement.** Quantitative and qualitative data confirmed the existence of clinical 'gatekeeping'
10	'Case' management (booking people on the course, sending letters, follow-up)	–	Facilitators had trouble protecting time for individual-level case management, which was labour intensive	**Silence.** Quantitative data did not speak to case management

| Logic model construct | Data | | Convergence code |
	Quantitative	Qualitative	
Immediate outcomes (see the section Immediate outcomes, except where stated otherwise)			
11 Quality of STEPWISE training maintained	–	The research project did not incorporate a system of continuous quality assurance	**Silence.** Quantitative data did not speak to quality assurance arrangements
12 Sessions delivered in line with the STEPWISE philosophy ('fidelity')	Mean (SD) facilitator talk time (DOT score) was 47.6% (12.26%). Mean percentage (SD) of facilitator behaviours that were deemed positive was 54.1% (17.67/35 items)	LDC staff indicated that facilitators sometimes gave insufficient time to action-planning or for the participant to answer questions – often offering, rather than eliciting, solutions. Facilitators reported that the highly-structured character of the intervention was challenging and acknowledged deviation	**Partial agreement.** DOT scores were difficult to interpret, but data of both types indicate that fidelity was not complete, with a highly structured intervention proving challenging to some staff, who were used to more professional autonomy
13 Attendance at all foundation and booster sessions; one-to-one telephone support sessions with demonstrable in-session 'receipt' of behaviour change content ('dose received')	82.6% of participants ($n = 171$) attended at least two sessions. 36 (17.4%) allocated to the intervention were non-attenders, whereas 111 (53.6%) attended ≥ 3 core sessions and ≥ 1 booster session. 3218 support contacts were made, with 169 participants (81%) receiving one or more contact. 167 (81%) had at least one telephone contact (average of 15). 105 participants (50.7%) received at least one mail contact (average of five) and 68 (32.9%) received a minimum of one face-to-face support contact (average of three)	Adequate strategies to understand participant 'receipt' (understanding and internalisation) of behaviour change content not in place	**Dissonance.** Quantitative data show us that most people attend; qualitative data show our lack of understanding about whether or not they understand or can use the intervention skills
14 4 × weekly foundation and three 'booster' sessions; one-to-one telephone support calls made ('dose delivered')	All foundation sessions were delivered; one booster session did not run. Not all support contacts were delivered. Facilitators found it difficult to contact some participants; however, there was incidence of non-compliance (such as first attempt to contact not being personalised and failure to conduct contacts)	Interviews with facilitators indicate that sessions were delivered, but a large number of support contact attempts were unsuccessful	**Partial agreement.** Qualitative research shows that support contact metrics must be interpreted with caution

TABLE 37 Triangulation table (*continued*)

Logic model construct	Data		Convergence code
	Quantitative	Qualitative	
15 Eligible people were invited to attend the STEPWISE programme ('reach')	414 out of 1223 potentially eligible service users were randomised. Estimates of potentially eligible service users varied significantly between trusts for which data were available (1233–12,968). Target vs. actual recruitment at these sites was 40 out of 36, 50 out of 45 and 42 out of 35, respectively	–	**Silence.** Qualitative data did not speak to reach
Selected intermediate outcomes (see Outcomes and estimation and Perceived effectiveness)			
16 Physical activity	Accelerometry shows no statistically significant difference between the intervention and control groups	Qualitative research participants claimed to have achieved changes in physical activity	**Dissonance.** Data types suggest different outcomes
17 Nutrition	DINE shows no statistically significant difference between the intervention and control groups	Qualitative research participants claimed to have achieved dietary changes	**Dissonance.** Data types suggest different outcomes
18 Weight	No statistically significant difference between the intervention and control groups	Qualitative research participants claimed to have achieved weight loss; for most, this was not borne out by quantitative evidence, or the weight loss was not clinically significant	**Dissonance.** Data types suggest different outcomes

Lapses in fidelity included giving insufficient time to answer questions and giving, rather than eliciting, solutions from participants (12). STEPWISE has no reliable mechanisms by which facilitators can investigate whether or not participants understand or can use the intervention (13).[24] Scheduled sessions went ahead but, when support contacts were attempted, they were not always successful (14). During the trial period, we reached a small fraction of those who were potentially eligible in the study areas (15).

Although many participants claimed to have achieved important changes in physical activity levels, nutrition and weight, quantitative data showed that this was true only for a minority and that any differences between trial groups could not be explained by receipt of the STEPWISE intervention.

Chapter 6 Results of the health economic analysis

Health-related quality of life

The EQ-5D-5L utility scores (*Table 38*) at the 3-month follow-up point were slightly higher in the intervention group (0.81 in the intervention group vs. 0.79 in the control group); however, at the 12-month point, there was no difference between the tariff values of the two groups (0.793 in the intervention group vs. 0.794 in the control group). At baseline, the EQ-5D-5L score was higher in the intervention group than in the control group, which has a negative effect on the cost-effectiveness calculations that consider the level of QoL (measured by the tariff) before the intervention. The total QALYs were very similar over the 12-month period, with a slight advantage for the intervention group.

TABLE 38 The EuroQol-5 Dimensions, five-level version tariffs at all time points and total QALYs

Time point	Trial arm, mean (SD)		All, mean (SD)
	Treatment	Control	
Baseline	0.79 (0.20)	0.78 (0.19)	0.79 (0.19)
3 months	0.81 (0.16)	0.79 (0.21)	0.80 (0.19)
12 months	0.79 (0.24)	0.79 (0.24)	0.79 (0.24)
Total QALYs	0.81 (0.012)	0.79 (0.015)	0.80 (0.010)

Short Form questionnaire-36 items questionnaire and Short Form questionnaire-6 Dimensions measure of quality of life

Short Form questionnaire-6 Dimensions scores, in contrast to the EQ-5D scores, were slightly higher in the control group (0.01 tariff points) than in the intervention group at baseline. Tariff scores also appear to be 0.02 tariff points higher in the intervention group at the 3- and 12-month follow-up periods. There is still only a very small advantage in the QALYs of the intervention group when using the SF-36 questionnaire to calculate a SF-6D QALY (*Table 39*). It is of interest that the tariffs using the SF-6D are substantially lower than those obtained from the EQ-5D, but this is in line with earlier findings.[128]

TABLE 39 Short Form questionnaire-6 Dimensions tariffs at all time points and total QALYs

Time point	Trial arm, mean (SD)		All, mean (SD)
	Treatment	Control	
Baseline	0.61 (0.005)	0.62 (0.005)	0.62 (0.004)
3 months	0.63 (0.005)	0.61 (0.006)	0.62 (0.004)
12 months	0.63 (0.006)	0.61 (0.005)	0.62 (0.004)
Total QALYs	0.63 (0.005)	0.61 (0.006)	0.62 (0.004)

Costs

Intervention costs

For the base case, the unit cost of two facilitators providing the intervention was provided, assuming that a group of four participants attended the intervention and the cost of facilitators was based on the wages of a mental health nurse. In this case, the cost of the intervention is around £35.20 per patient per hour and £88 for a full 2.5-hour session. The mean cost of the intervention is £565 for the base case. The maximum cost of the intervention, in the base-case scenario, is £616 for seven full sessions and £283.20 for 24 support contacts at a price of £1.18 per minute for 10 minutes.

Health and social care costs and lost work/education

Table 40 shows the number and percentage of service users accessing each type of care, the mean number of contacts with the service for those using it, and the mean cost of the service across all participants. Less frequently visited health-care professionals were combined into one category: other health-care professionals. This category includes drug advisors, other counsellors, home treatment teams, outreach workers, intervention therapists, occupational therapists, drug service facilities and community mental health support workers. The costs of social care were combined into another category, including day care, drop-in centre, self-help group, leisure groups, adult classes and other types of care. The number of contacts for the intervention is shown separately for each time point and represents the number of full sessions attended in the case of the intervention group. However, the cost calculations for other health-care services take into account patients attending part of a session.

At baseline, the most frequently consulted health professionals were GPs (68% in the intervention arm and 67% in the control arm), psychiatrists (61% in the intervention arm and 60% in the control arm) and mental health nurses (58% in the intervention arm and 60% in the control arm). At baseline, 20% of participants in the intervention group and 17% in the control group accessed social care. Fifty per cent of participants in the intervention group accessed other health-care professionals and 49% in the control group did so.

At the 3-month follow-up, the most frequently consulted health professionals were still GPs (46% in the intervention arm and 54% in the control arm), psychiatrists (41% in the intervention arm and 43% in the control arm) and mental health nurses (42% in the intervention arm and 47% in the control arm). At the 3-month follow-up, 13% of participants in the intervention group and 14% of those in the control group (a slightly lower proportion than at baseline) accessed social care. Thirty per cent of participants in the intervention group and 32% in the control group accessed other health-care professionals. Overall, the level of participants reporting use of all of these categories of services was slightly lower in both groups.

At the 12-month follow-up, the most frequently consulted health professionals remained GPs (reported by 62% in the intervention group and 64% in the control group), psychiatrists (reported by 60% in the intervention group and 56% in the control group) and mental health nurses (reported by 47% in the intervention group and 56% in the control group). At 12 months, 14% of participants in the intervention group and 15% in the control group accessed social care. According to self-reported data, 33% of participants in the intervention group and 38% in the control group accessed other health-care professionals. At baseline, 43% of participants in the intervention and 49% in the control group group reported receiving informal, largely unpaid, care. The same percentages also reported this at the 3-month follow-up. At the 12-month follow-up, 65% of the intervention group and 59% of the control group reported receiving informal care.

Table 40 also includes productivity losses, which are the cost of lost work and education time of participants in the study and informal care received from carers. As informal carers are largely unpaid, productivity losses relating to informal care indicate that the amount of money that could have been gained by working during the time that informal care is provided (i.e. the opportunity cost of caring for the service user). At baseline, 56% of participants in the intervention group and 61% in the control group were employed. By the end of the study, these figures had fallen slightly to 43% in the intervention group and 49% in the control group. At baseline, 13% of participants reported that they were working and

TABLE 40 Health and social care service use and productivity losses

| | Health and social care service use and productivity losses during the 3 months pre randomisation | | | | | |
| | Trial arm, *n* (%) of participants using services | | Trial arm, mean (SD) contacts for those using services | | Trial arm, mean (SD) costs (£) for all participants (2015–16 pounds sterling) | |
Category of service use	Treatment	Control	Treatment	Control	Treatment	Control
GP	142 (68)	138 (67)	2 (0.2)	3 (0.2)	83 (9)	90 (9)
Psychiatrist	127 (61)	122 (60)	2 (0.2)	2 (0.2)	94 (14)	89 (10)
Psychologist	25 (12)	27 (13)	5 (0.8)	4 (0.7)	67 (19)	53 (13)
Other doctor	16 (8)	14 (7)	2 (0.3)	3 (0.8)	8 (3)	10 (4)
Mental health nurse	121 (58)	121 (59)	6 (0.8)	4 (0.3)	172 (38)	137 (22)
Social worker	41 (20)	35 (17)	4 (0.5)	5 (0.9)	52 (14)	91 (30)
Other health-care professional[a]	104 (50)	99 (48)	5 (0.7)	4 (0.5)	308 (55)	196 (28)
Inpatient (days)	6 (3)	12 (6)	28 (37)	28 (30)	324 (183)	658 (242)
Medication	206 (99)	199 (97)	N/A	N/A	408 (26)	397 (29)
Other health and social care services[b]	76 (37)	69 (34)	14.8 (2.0)	12.3 (1.4)	308 (55)	195 (28)
Informal care (hours per week)	117 (56)	125 (61)	10.4 (1.1)	10.8 (1.5)	912 (1597)	1019 (2218)
Lost employment (days)	27 (13)	26 (13)	2.6 (1.4)	6.3 (2.8)	29 (223)	66 (453)
Lost education (days)	25 (12)	13 (63)	5.4 (3.3)	1.9 (1.6)	54 (34)	10 (9)
Police	3 (14)	6 (29)	1.7 (0.7)	1.2 (0.2)	2 (1)	1 (1)
Total health and social care[b]	208 (100)	202 (99)			1623 (236)	1802 (260)
Total societal	208 (100)	205 (100)			2619 (258)	2900 (315)
	Health and social care service use and productivity losses during the 3 months post randomisation					
	Trial arm, *n* (%) using services		Trial arm, mean (SE) contacts for those using services		Trial arm, mean (SE) costs (£) for all participants (2015–16 pounds sterling)	
Category of service use	Treatment	Control	Treatment	Control	Treatment	Control
GP	96 (46)	112 (54)	2 (0.2)	2 (0.1)	83 (9)	90 (10)
Psychiatrist	86 (41)	90 (43)	3 (1.1)	1.2 (0.3)	94 (14)	89 (10)
Psychologist	15 (7)	16 (8)	4 (0.9)	6 (1.1)	67 (19)	53 (13)
Other doctor	15 (7)	14 (7)	2.4 (0.9)	1.6 (0.4)	7 (3)	10 (4)
Mental health nurse	88 (42)	98 (47)	6 (1.1)	5 (0.5)	172 (39)	136 (22)
Social worker	27 (13)	29 (14)	9 (3)	4 (0.9)	52 (14)	91 (30)
Other health-care professional[a]	62 (30)	67 (32)	2 (0.4)	3 (0.7)	304 (55)	195 (28)
Inpatient (days)	7 (3)	8 (4)	18 (32)	7 (10)	238 (157)	112 (57)
Medication	177 (86)	168 (85)	N/A	N/A	159 (21)	175 (24)
Other health and social care services[b]	82 (40)	46 (23)	15.0 (1.9)	13.2 (1.4)	304 (55)	195 (28)
Informal care (hours per week)	106 (52)	114 (58)	13.3 (1.8)	12.2 (2.1)	1038 (2264)	1018 (2671)
Lost employment (days)	5 (2)	11 (6)	1.6 (0.9)	6.9 (3.4)	19 (11)	86 (44)

TABLE 40 Health and social care service use and productivity losses (*continued*)

| | Health and social care service use and productivity losses during the 3 months post randomisation | | | | | |
| | Trial arm, *n* (%) using services | | Trial arm, mean (SE) contacts for those using services | | Trial arm, mean (SE) costs (£) for all participants (2015–16 pounds sterling) | |
Category of service use	Treatment	Control	Treatment	Control	Treatment	Control
Lost education (days)	3 (1)	1 (0.5)	1.25 (0.8)	0.8 (0.8)	6 (4)	3 (3)
Police	7 (3)	5 (2)	1.3 (0.3)	2.0 (0.6)	3 (2)	2 (1)
Intervention	174 (85)	–	2.83 (0.1)	–	305 (7)	–
Total health and social care[b]	205 (100)	195 (98)			1640 (197)	1133 (100)
Total societal	205 (100)	198 (100)			2599 (248)	2135 (214)
	Health and social care service use and productivity losses between 3 and 12 months post randomisation					
	Trial arm, *n* (%) using services		Trial arm, mean (SE) contacts for those using services		Trial arm, mean (SE) costs (£) for all participants (2015–16 pounds sterling)	
Category of service use	Treatment	Control	Treatment	Control	Treatment	Control
GP	128 (62)	133 (64)	4 (0.4)	5 (0.5)	132 (15)	150 (19)
Psychiatrist	124 (60)	116 (56)	3 (0.3)	2 (0.2)	123 (14)	111 (13)
Psychologist	29 (14)	22 (11)	11 (3)	9 (2)	176 (56)	92 (27)
Other doctor	24 (12)	22 (11)	2 (0.4)	3 (0.5)	15 (4)	19 (6)
Mental health nurse	97 (47)	102 (49)	6 (1.1)	5 (0.5)	107 (30)	270 (73)
Social worker	30 (14)	31 (15)	9 (3)	4 (1)	75 (22)	107 (30)
Other health-care professional[a]	69 (33)	79 (38)	8 (2)	8 (2)	390 (95)	413 (136)
Inpatient (days)	18 (8)	14 (7)	20 (7)	25 (8)	670 (251)	607 (249)
Medication	204 (98)	195 (97)	N/A	N/A	1080 (67)	1033 (82)
Other health and social care services[b]	51 (25)	59 (29)	43.7 (8.2)	33.3 (4.8)	390 (95)	413 (135)
Informal care (hours per week)	90 (43)	99 (49)	13.2 (1.9)	10.9 (1.3)	1038 (2264)	1018 (2671)
Lost employment (days)	12 (6)	14 (7)	6.9 (3.6)	20.8 (10.8)	77 (42)	237 (128)
Lost education	3 (1)	4 (2)	1.8 (1.1)	2.0 (1.2)	7 (5)	7 (4)
Police	7 (3)	6 (3)	2.7 (0.8)	1.8 (0.4)	28 (8)	4 (2)
Intervention	174 (85)	–	1.43 (0.1)	–	273 (13)	–
Total health and social care[b]	208 (100)	200 (99.5)			3616 (353)	3319 (387)
Total societal	208 (100)	201 (100)			8734 (898)	8170 (863)

N/A, not applicable; SE, standard error.
a Drug and alcohol advisor, other counsellor, home treatment team. Assertive outreach, early intervention team, occupational therapist.
b Drug/alcohol service, community mental health centre, day care centre, drop-in centre, self-help/support group, leisure centre group, adult education.
Note
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124

missing work because of illness in the intervention group and 13% reported this in the control group. This was reported at similar levels (12% in the intervention group and 14% in the control group) at the 12-month follow-up. At baseline, 12% of participants in the intervention group and 13% in the control group attended further education, mostly further education colleges. At baseline, the proportion of participants who reported that they were unable to attend further education college because of illness was 4% in the intervention group and 2% in the control group. At the 12-month follow-up, the percentage of participants in further education and missing one or more days of education was 2% in both the intervention group and the control group.

Health and social care costs included the costs of medicines and of visits to NHS professionals in primary and community care and inpatient settings, as well as social care costs. Over the follow-up period, the mean total health and social care costs were £5255 in the intervention group and £4453 in the control group. Societal costs were calculated using police costs, productivity losses from lost education and employment and informal care costs. The mean total societal costs were £11,332 in the intervention group and £10,305 in the control group. The cost differences were partly attributable to the intervention, but were also caused by greater use of other services.

The differences in health and social care and societal costs are not significant. For health and social care costs, the difference (after controlling for baseline) was £870.39 (p-value = 0.132, bootstrapped CI –£262 to £2003). For societal costs, the difference (after controlling for baseline) was £1295.37 (p-value = 0.33, bootstrapped CI –£1329 to £3919).

Cost-effectiveness analysis

The net benefit approach was used in order to produce cost-effectiveness planes and CEACs. Multiple imputation (chained equations) was applied to the cost and QoL data.

Cost-effectiveness results based on the EuroQol-5 Dimensions, five-level version

The incremental costs and QALYs are shown in *Table 41*. The ICER from the health-care perspective is £246,921 per QALY and from the societal perspective is £367,543 per QALY.

The bootstrapped replications of the difference in health and social care costs range from £433 to £1392. The bootstrapped replications of the difference in EQ-5D QALYs range from –0.012 to 0.013 (*Figure 26*). It is clear that the intervention is cost-increasing and results in better or worse outcomes to a similar extent. The line shown on the scatterplot represents the NICE threshold, below which the replicates should fall for the intervention to be cost-effective. No replications fall below this line. The probability that the STEPWISE intervention is cost-effective is 0% at the £20,000 threshold set by NICE, as shown by *Figure 27*. The probability that the intervention is cost-effective is still only 17% at a threshold of £200,000 when the analysis is conducted from the health-care perspective.

TABLE 41 Cost-effectiveness results at 1 year (QALYs)

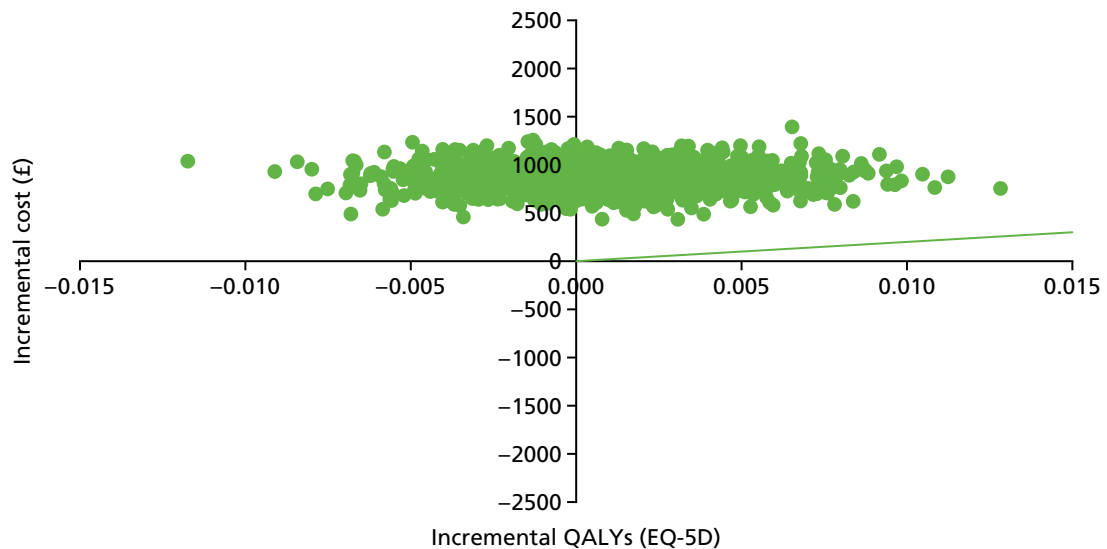| Outcome: QALYs from the EQ-5D-5L	Treatment vs. control
Incremental effect	0.0035234
Incremental health-care cost	£870
ICER (health care)	£246,921
Incremental societal cost	£1295
ICER (societal)	£367,543

FIGURE 26 Cost-effectiveness plane for EQ-5D QALYs from the health and social care perspective.
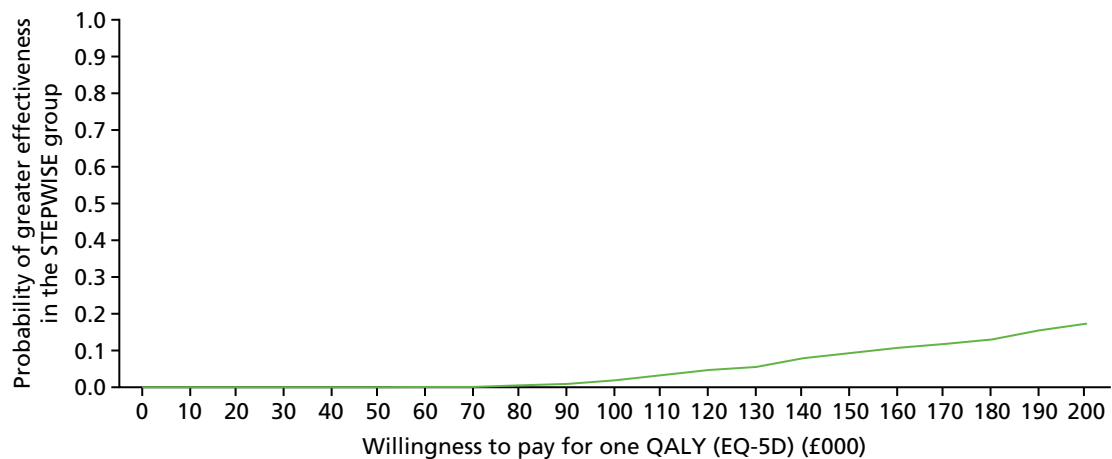

FIGURE 27 Cost-effectiveness acceptability curve for EQ-5D QALYs from the health and social care perspective.

The ICERs for the societal perspective showed similar results to those for the health-care perspective. The bootstrapped replications of the difference in societal costs range from £192 to £2382. The bootstrapped replications of the difference in EQ-5D QALYs range from –0.012 to 0.013 (*Figure 28*). Again, the intervention results in higher costs and approximately equal likelihoods of better or worse outcomes. We have not shown an ICER line, as NICE does not take a societal perspective. However, the probability that the STEPWISE intervention is cost-effective is 0% at a £20,000 threshold (*Figure 29*). The probability that the intervention is cost-effective is still only 7% at a threshold of £200,000 when the analysis is conducted from the societal perspective.

Cost-effectiveness results based on the Short Form questionnaire-6 Dimensions

Health and social care perspective
The bootstrapped replications of the difference in health and social care costs range from £433 to £1392. A total of 1000 bootstrapped replications of both the costs and the QALYs were performed. The bootstrapped replications of the difference in SF-6D QALYs range from 0.003 to 0.012 QALYs (*Figure 30*). *Table 42* shows the SF-36 QALY outcomes at 1 year. It is clear that the intervention is cost-increasing and results in better or worse outcomes to a similar extent. The line shown on the scatterplot represents the NICE threshold, below which the replicates need to fall for the intervention to be cost-effective. No replications fall below this line.
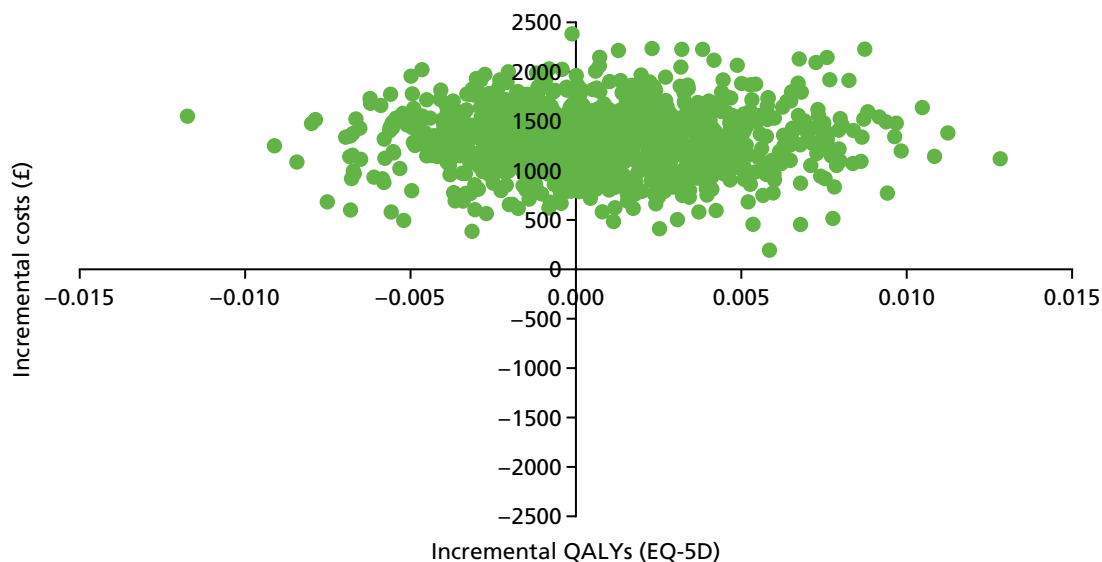
FIGURE 28 Cost-effectiveness plane for EQ-5D QALY from the societal perspective.
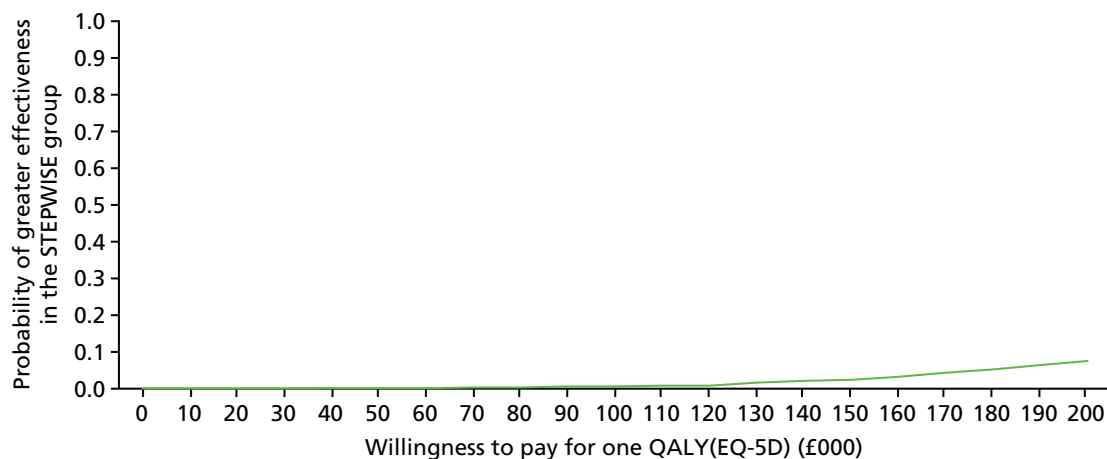

FIGURE 29 Cost-effectiveness acceptability curve for EQ-5D QALY from the health and social care perspective.
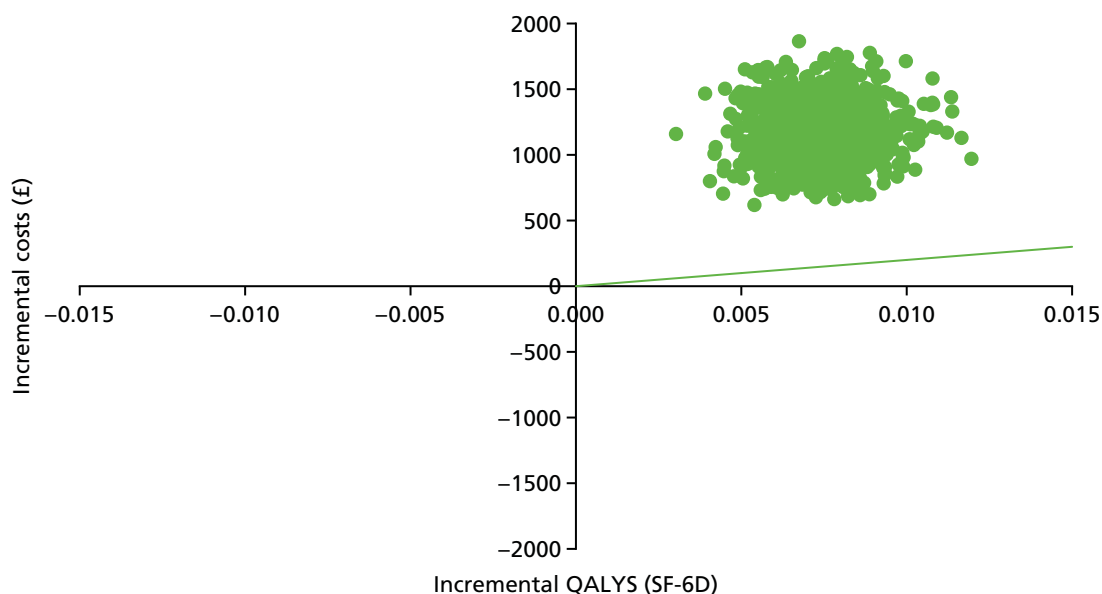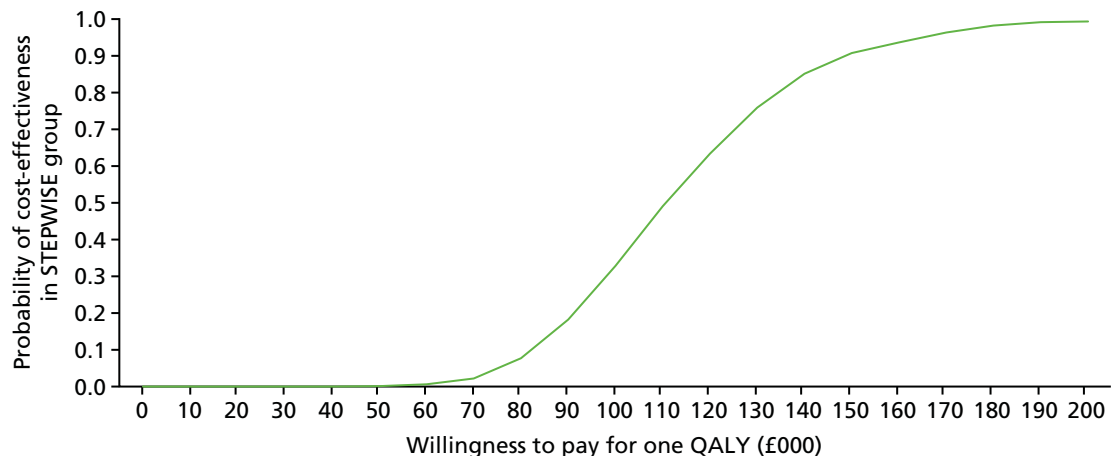

FIGURE 30 Cost-effectiveness plane for SF-6D QALYs from the health and social care perspective.

TABLE 42 Cost-effectiveness results at 1 year (QALYs from the SF-6D)

Outcome: QALYs from the SF-6D	Treatment vs. control
Incremental effect	0.0148241
Incremental health-care cost	£870
ICER (health care)	£58,688
Incremental societal cost	£1295
ICER (societal)	£87,358

The probability that the STEPWISE intervention is cost-effective is therefore, 0% at the £20,000 per QALY threshold set by NICE, as shown by *Figure 31*. The probability that the intervention is cost-effective is 50% at a threshold of £110,000 per QALY and 99% at a threshold of £200,000 per QALY when the analysis is conducted from the health-care perspective.

FIGURE 31 Cost-effectiveness acceptability curve for SF-6D QALYs from the health and social care perspective.

Societal perspective

The bootstrapped replications of the difference in societal costs range from £403 to £1667. The bootstrapped replications of the difference in SF-6D QALYs range from 0.003 to 0.012 QALYs.

The probability that the STEPWISE intervention is cost-effective is 0% at the £20,000 threshold set by NICE, as shown by *Figure 32*. The probability that the intervention is cost-effective is 74% at a threshold of £200,000 when the analysis is conducted from the societal perspective (*Figure 33*).
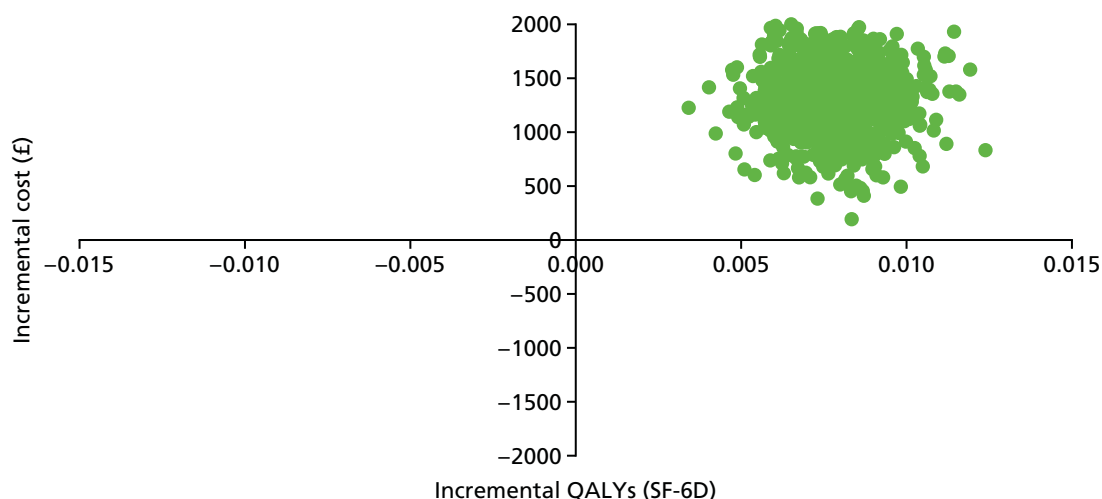
FIGURE 32 Cost-effectiveness plane for SF-6D QALYs from the societal perspective.
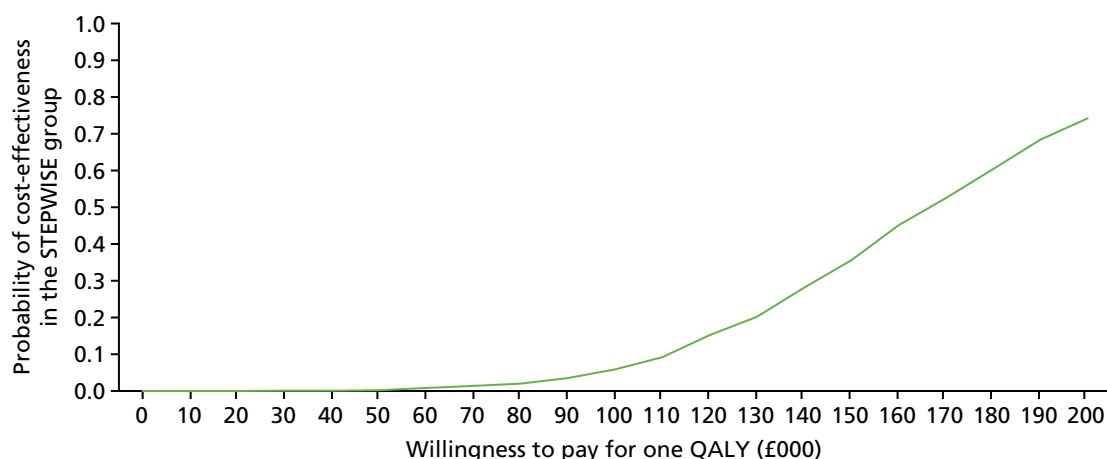
FIGURE 33 Cost-effectiveness acceptability curve for SF-6D QALYs from the societal perspective.

Sensitivity analysis

Table 43 shows the different outcomes for the ICER and the optimal strategy if the costs of the intervention and the group size attending the intervention are varied in the health and social care perspective. The table also shows how varying the cost of informal care and lost employment days affects the outcomes if the cost of the intervention is held constant at the price of a group of four patients receiving the course from two mental health nurses. Attendance of sessions was low, with only 53.6% of patients attending more than three main sessions and one or more booster sessions. Therefore, the base case assumed an attendance of four patients rather than the six planned for in the study design.

TABLE 43 Sensitivity analysis (STEPWISE vs. TAU)

Health-care perspective (EQ-5D)					
		Unit cost, £ (per hour)	Incremental		
Profession	Group size		Cost (£)	Benefit	ICER (£)
Mental health nurse	4	35	870	0.0035234	246,921
Mental health nurse	6	24	746	0.0035234	211,727
Mental health nurse	8	18	685	0.0035234	194,414
Societal perspective (EQ-5D, assuming a group of four patients)					
		Unit cost, £ (per hour)	Incremental		
Informal care wage rate	Employment wage rate		Cost (£)	Benefit	ICER (£)
Average	Average	12	1295	0.0035234	367,543
Minimum	Minimum	7	785	0.0035234	222,796
Health-care worker	Minimum	20	795	0.0035234	225,634
Health-care perspective (SF-6D)					
		Unit cost, £ (per hour)	Incremental		
Profession	Group size		Cost (£)	Benefit	ICER (£)
Mental health nurse	4	35	870	0.0148241	58,688
Mental health nurse	6	24	746	0.0148241	50,323
Mental health nurse	8	18	685	0.0148241	46,209
Societal perspective (SF-6D, assuming a group of four patients)					
		Unit cost, £ (per hour)	Incremental		
Informal care wage rate	Employment wage rate		Cost (£)	Benefit	ICER (£)
Average	Average	12	1295	0.0148241	87,358
Minimum	Minimum	7	785	0.0148241	52,954
Health-care worker	Minimum	20	795	0.0148241	53,629

Chapter 7 Discussion

Conduct of the trial

The STEPWISE trial was a complex trial, which faced many challenges. Previous studies have suggested that the recruitment and retention of people with schizophrenia are difficult. In addition to this generic problem, the STEPWISE trial faced the additional challenge of recruiting in short waves because of the nature of the group intervention. We recognised that, if recruitment took too long, those who were recruited first would have to wait for a group to start and may lose interest by the time the intervention started. We also recognised the importance of delivering the intervention before the 3-month follow-up visits. Consequently, a concentrated period of recruitment was needed at each site to overcome this.

The STEPWISE trial was undertaken in 10 locations across England, covering both the north and south of England, rural and urban settings and mixed ethnic populations. Although this had the strength of representing the diversity of the NHS, it posed logistical challenges for the conduct of the trial, requiring robust organisation at sites and the Sheffield CTRU.

In STEPWISE, we used the methodology designed to develop interventions for people with, or at risk of, diabetes mellitus. At the outset, it was unclear whether or not it would be possible to transfer this process to a different disease area, namely schizophrenia. The intervention development phase showed that this was achievable, but it took 3 months longer than originally anticipated.

Despite the challenges of recruitment, the trial recruited 414 participants (original target: 396) in just over 1 year, which was almost 3 months quicker than planned. This illustrates the level of interest for such interventions among people with schizophrenia and mental health care professionals. Previous studies have indicated that people with psychotic illness have the same level of interest in their physical health, but struggle to prioritise this over other issues, such as their mental illness.

Following successful recruitment, 341 participants (81.6%) completed the trial. This retention was similar to our original estimates and other intervention studies for people with schizophrenia.[55] A total of 20 participants were lost to follow-up, 48 withdrew consent and three died. The reason for withdrawal of consent was often the worsening of mental illness precluding attendance at research assessments.

A strength of the STEPWISE trial was the use of an objective primary outcome measure, which could not be greatly affected by knowledge of the intervention.[129] Although participants were not blinded, the STEPWISE assessors were blinded and largely remained blind during follow-up, further reducing the risk of observer bias.[130]

As a result, the STEPWISE trial is the largest trial of weight management in severe mental illness of its kind. It was adequately powered to answer the hypothesis we posed at its outset. Furthermore, through the use of sensitivity analyses, even under extreme assumptions about missing data, the results of the trial would be unchanged.

Summary of the findings

The STEPWISE intervention was neither clinically effective nor cost-effective over the 12-month trial period. Both groups lost an average of 0.5 kg, suggesting that there may have been a small benefit to participation in the trial, given the known trajectory of weight gain for people taking antipsychotics,[131] but there was no difference in weight change between groups. To achieve weight reduction, the intervention needed to

promote changes in dietary intake, physical activity or both. The baseline data confirmed that the trial participants were eating a diet that was high in refined carbohydrates and low in fibre. In addition, the accelerometry data indicated that they were physically inactive, with levels of activity similar to older adults from the general population aged 75–79 years.[132] The imprudent diet and physical inactivity provided substantial opportunity for change, but there was no sustained behaviour change in either of these crucial behaviours. Furthermore, the intervention did not lead to changes in other biomedical outcomes, psychiatric well-being, QoL or obesity perception.

The estimated cost of the STEPWISE programme was £565, but the intervention was not cost-effective, owing to the relatively small effect of the intervention on the (EQ-5D-5L) QoL measure (a QALY difference of around 0.0035 between the treatment and control groups after controlling for baseline utility scores) and increased costs of other services. This results in an ICER of > £200,000 in the base-case analysis.

The lack of effect on weight contrasts with previous reports that suggested that lifestyle interventions could help people with severe mental illness to lose weight. The STEPWISE study drew heavily from the experience published in the meta-analysis by Caemmerer *et al.*,[12] which reviewed 17 studies and included 810 people receiving antipsychotics. This paper found that lifestyle interventions led to significant weight reduction, in association with concomitant improvements in cardiovascular risk factors. However, most of the studies were of short duration, with most lasting for 12–16 weeks, and included a small number of participants (median 53, range 15–110).

The 2014 NICE guidance for psychosis and schizophrenia in adults[14] included 24 studies and came to similar conclusions. Both reviews included studies that had recruited on the basis of antipsychotic treatment rather than diagnosis, and so significant numbers of participants had other types of mental illness. This is important, as the strategies needed to promote weight loss in people with schizophrenia may be different. NICE comments that few studies examined weight change beyond 6 months, and only six included > 100 participants. With relevance to the NHS, no study was conducted in the UK. There was a moderate risk of bias for most studies and there was substantial heterogeneity of effect size. The evidence review concluded that lifestyle interventions were effective in reducing and maintaining body weight in the short term, but, without longer-term data, effects beyond 6 months were unknown. Despite the limitations in the evidence, based on expert opinion, NICE recommends that mental health-care services should offer a combined healthy eating and physical activity programme to people with severe mental illness, particularly if they are taking antipsychotics.[14]

The length of follow-up of the STEPWISE trial allowed a longer-term perspective, which addressed some of the shortfalls of earlier studies. Over the course of the STEPWISE trial, several other long-term studies examining the effect of lifestyle interventions were published and are included in the most recent systematic review.[15] Six studies reported that interventions lasting for more than 1 year showed a more consistent weight reduction (SMD = −0.24, 95% CI −0.36 to −0.12), although only two of the six studies recorded a statistically significant weight loss, both of which included substantial numbers of people with other severe mental illnesses.

Given the unexpected results of the STEPWISE trial, we examined why the intervention failed, in order to inform future research and clinical practice. The first question is whether or not the intervention was fit for purpose.

Development and implementation of the intervention
The STEPWISE programme meets most of the Department of Health and Social Care guidelines,[17] on which its parent programme, DESMOND,[19] was based. It is theory driven (see *The intervention's theory of change*) and evidence based (see *Intervention development*), coproduced with patients and flexible to emerging individual needs (see *Intervention development*). Its specific aims and objectives are shared with users and it supports self-management attitudes, beliefs, knowledge and skills for the user (see *Intervention development*).[17] The structured, written curriculum incorporates the assessment of individual learning

needs and can be flexibly applied, meeting diverse needs (see *Intervention development*). It appears to be reliable, valid, relevant and comprehensive and uses different teaching media and supporting materials (see *Table 35*). However, staff raised questions about its resource efficiency (see *Chapter 5*, *Appraisal work*) and the health economic model (see *Chapter 6*, *Cost-effectiveness analysis*).

The STEPWISE facilitators demonstrated an understanding of empowerment philosophy[133–135] (see *Chapter 5*, *Facilitator views of STEPWISE*, *Sense-making*), but perhaps lacked an understanding of the behaviour change theories that underpinned the intervention. It is possible that a narrow interpretation of empowerment, as autonomous change driven by intrinsic motivation, deprived some participants of more external support that they desired (see *Chapter 5*, *Facilitator views of STEPWISE*, *Sense-making*) and of effective behaviour change techniques such as monitoring by, and feedback from, others (see *Chapter 5*, *Facilitator views of STEPWISE*, *Appraisal work*). If such case-by-case adaptations are a matter of informed choice, then they should not be seen as a departure from empowerment philosophy.

Although a participatory approach to intervention design involved service users, a potentially 'over-controlled' intervention,[136] in which the work as done was different from the work as imagined,[137] may have been prevented by participatory implementation and adaptation during the trial itself.[138–141] Although the developers considered the course to be of low intensity and modest in cost, at a time when NHS mental health trusts were under considerable pressure,[142,143] some struggled to release resources, making programme management difficult for front-line staff (see *Chapter 5*, *Facilitator views of STEPWISE*, *Operational work*).

The training was well received, and the delivery of programme content in line with empowerment philosophy principles was evident (see *Chapter 5*, *Activities*, Trainers train and periodically assess fidelity of facilitators). A quality assurance programme was developed with relevant assessment criteria. The user experience was described positively in general (see *Chapter 5*, *Participant acceptability*), but this was audited as part of this evaluation, not as part of the intervention. Routine auditing of content comprehension, behaviour change and clinical outcomes formed no part of the intervention programme, meaning that facilitators could not appraise its effects (see *Chapter 5*, *Appraisal work*).[24,80]

Staff tailored the intervention appropriately for individuals, whose views and experiences were mostly valued, which is an important marker of quality. Although the pace of delivery could not always be adjusted to everyone's needs, many participants found that the duration of support was acceptable, although in some cases it may not have been adequate to develop and apply behaviour change strategies that would lead to lasting benefits.[144]

The two successful long-term trials employed interventions that were considerably more intensive than STEPWISE, and a more intensive intervention may have achieved better results. The ACHIEVE study by Daumit *et al.*[145] included 291 participants who were seen in 10 community psychiatric rehabilitation outpatient programs. The intervention, which involved a combination of group weight management sessions (weekly in the first 6 months, then monthly), monthly individual visits and thrice-weekly group activity classes, achieved a mean weight loss of –3.2 kg over 18 months. The more recent STRIDE study[146] included 56 men and 144 women who were randomised to routine care or a 6-monthly weekly group intervention plus six monthly maintenance sessions. STRIDE intervention participants lost 4.4 kg more than control participants from baseline to 6 months (95% CI –6.96 to –1.78 kg), but this difference was reduced to 2.6 kg by 12 months (95% CI –5.14 to –0.07 kg). Further evidence in favour of a more intensive programme comes from a service evaluation of a UK-based weight management programme in which the only predictor of weight loss was the number of sessions attended.[53] Many participants valued the group sessions and the opportunities to interact with others with the same condition; however, there was a breadth of understanding and ability to learn. For some participants, one-to-one sessions, with greater attention to memory support, may have proved more effective. However, intensity may not provide the whole explanation. The Danish CHANGE trial[147] randomised 428 people with schizophrenia spectrum disorders and abdominal obesity to 12 months of intensive lifestyle coaching plus care co-ordination plus usual care, or care co-ordination and usual care, or usual care alone. In the lifestyle coaching arm, the

participants were offered contact with a team member for 1 year. These personal one-to-one contacts occurred at least once per week and typically lasted for up to 1 hour. Despite the similar intensity to the ACHIEVE and STRIDE studies, neither lifestyle coaching nor care co-ordination reduced body weight or waist circumference.

Another alternative explanation may lie in the diagnoses of the participants. Unlike the STEPWISE and CHANGE studies, which recruited only people with schizophrenia spectrum disorder, ACHIEVE and STRIDE included significant numbers of people with other psychiatric disorders. Only 58.1% of the participants in the ACHIEVE study had schizophrenia or schizoaffective disorder, and one-third of participants had a mood disorder. Only 29% of the STRIDE participants had schizophrenia spectrum disorders.

Given the current funding constraints within the NHS, it is debatable whether or not a more intensive intervention would have been affordable within a UK NHS setting and it is noteworthy that the total contact time in the STEPWISE sessions (17.5 hours) is similar to that recommended by the NICE prevention of diabetes mellitus guidance.[18] Even with the current number of STEPWISE sessions, fewer than one-quarter of participants attended all sessions, with more participants attending core sessions than booster sessions. This problem is not unique to the STEPWISE trial, and the level of engagement is similar to other group-based education programmes.[16,27,148]

Although the duration of illness and antipsychotic treatment was not reported in the ACHIEVE and STRIDE studies, differences in these factors may further explain the differences in results. We deliberately set out to include a broad range of people with schizophrenia to represent those in contact with NHS mental health services. Consequently, our participants had a wide spectrum of BMI, ranging from normal weight to morbid obesity. It is possible that, had we restricted our entry to the study to those with a BMI of 25–35 kg/m^2, the intervention may have proved more successful. Fifty-eight people had type 2 diabetes mellitus, for whom lifestyle intervention is key to self-management. Although there is overlap between obesity and diabetes mellitus management, there are areas in which this diverges and could lead to different results.

Most STEPWISE participants had a long history of an established psychiatric disorder, and it is possible that different approaches are required depending on disease duration. Weight gain is most rapid during the early phase of psychosis,[149,150] and this may be the time when lifestyle approaches are most effective. Although we planned to include individuals shortly after the diagnosis of first episode psychosis, very few participants had been on treatment for < 3 months, because of the need to recruit in waves for the group intervention.

Usual care and the risk of contamination
The trial followed best practice for pragmatic trials by allowing considerable leeway for alternative management strategies in the control arm.[34] The use in combination of the usual care survey,[36] the CSRI[43] and a weight loss programme CRF ensured that the treatment effect was not diluted by a control arm that was more active than intended.[151,152]

We undertook a survey of usual care to ascertain the physical health provision at each site. Although there was considerable variation between sites, none was compliant with the latest NICE guidance. To standardise usual care for control participants, the research team provided each participant with written lifestyle advice. Arguably, this went beyond usual care and it is possible that this brief intervention may have a small beneficial effect for control participants, thus minimising the observed effect of the trial. Participation in the trial may have heightened awareness of the obesity problem and led to changes in behaviour. The reduction in body weight in both arms, as opposed to the expected weight gain, suggests that this may have occurred.

Only 8.6% of participants attended weight loss programmes outside the trial, with a slightly higher proportion in the intervention group. There were a few ad hoc reports of referrals by GPs for diet advice or gym membership for those who were newly identified as having diabetes mellitus or prediabetes mellitus.

Other strengths of the trial

The trial results came as a surprise to investigators working at sites that had experienced benefits at their trust. At the results meeting, the investigators described how health-care professionals had become more engaged in weight management and how trusts had improved physical health monitoring. The STEPWISE programme had addressed both patient and care co-ordinator demand for weight management programmes and, in some cases, led to substantial weight reduction. The investigators also reported that participants overcame their anxiety of group-based sessions and reported the value of sharing experiences with other people with severe mental illness with similar weight problems. The social interaction of the groups undoubtedly had a positive effect for participants. The investigators reported how their own practice and personal lives had changed as a result of participation in the trial. They valued the opportunities for interaction between the clinical and research teams within the trust.

Strengths and weaknesses of the process evaluation

Following guidance,[68] we fully explored how context affected implementation and identified – as have others[153] – poverty, under-resourced public services and stigmatisation of people with diagnoses of mental illness as key issues. The process evaluation showed that the funding of transport and the patient-focused educational approach was popular with participants, but the scarcity of resources remains a problem for implementation.

The study used direct observation of STEPWISE sessions, the gold standard method for investigating intervention fidelity.[24] Although the intervention developers undertook the fidelity assessment, other aspects of the process evaluation were conducted by evaluators (DH and RG-W) who were sufficiently independent to observe the work of stakeholders critically, as recommended in the relevant guidance.[68] The process evaluation was informed by both programme theory and middle range theory, allowing some investigation of the causal assumptions that underpinned the intervention. However, the use of the Behaviour Change Wheel[95] in the analysis of participant transcripts was 'after the fact'; as it did not inform the topic guide, the associated analysis (see *Tables 33* and *34*) reflects the participants' patterns of attention rather than systematic elicitation of information based on all theoretical constructs.

Strengths and weaknesses of the economic analysis

Strengths

The high follow-up rate has generated reliable results; however, the use of the relatively new EQ-5D-5L tariffs to calculate the QALY values may mean that the results are not easily comparable with previous results of other studies using the EQ-5D-3L questionnaire, which gave participants three instead of five options to each question. With the extra options, the EQ-5D-5L is more sensitive to change than EQ-5D-3L.

Limitations

Information on service use was collected with questionnaires, which may limit the data accuracy. However, the CSRI method is a well-established method for collecting service use data and this is a data collection issue, which would affect both groups. We also accept that there may be some recall bias in the 9-month follow-up period between 3 and 12 months post randomisation, whereby patients found the number of appointments difficult to remember. There is no reason to suggest that there would be a difference between the treatment and control groups in this respect.

The EQ-5D is sometimes considered to be insensitive to changes in QoL in people with serious mental illness, in comparison with the SF-6D.[128] That is to say, many patients in the disease area report no problems in each area in the EQ-5D questionnaire, perhaps because the domains are less relevant than in other disease areas. The STEPWISE economic evaluation also used the SF-6D, but found a similarly small QALY difference between the two groups. As the STEPWISE intervention was aimed at improving physical health, we might expect to see more improvement than usual on the EQ-5D, which is more focused on physical symptoms, but this was not the case.

In STEPWISE, all participants received a lifestyle information booklet, which was not costed as part of the study. A nominal value was used to cost e-mail and postcard support contacts, which may not accurately represent the cost of the programme. As we did not have data on the wages or education levels of participants and carers, we used the common approach of taking average, minimum and home carer wage rates, but this may not present an accurate picture of the economic impact of the productivity losses. The benefits of lifestyle behaviour change may take longer to emerge than the intervention tested; however, it is unlikely that longer-term benefits would be observed, given the lack of short-term benefits.[147]

Implications for policy-makers, health professionals, people with schizophrenia and their families

The trial has important clinical implication for practice, despite being no closer to finding the best way to manage obesity and weight gain in people with schizophrenia. The STEPWISE trial has focused on lifestyle modification, as have previous studies, but this does not recognise the breadth of factors that contribute to weight gain and obesity. Antipsychotics are associated with significant weight gain, and broader approaches that combine individualised lifestyle modification with tailoring of antipsychotic treatment or co-prescription with drugs that reduce antipsychotic-associated weight gain may be needed.

Currently, NICE guidance recommends that mental health trusts should offer lifestyle interventions to people with psychotic illnesses.[14] Although it is clear that behavioural change to address the challenge of obesity is effective for some people with severe mental illness, STEPWISE has indicated how difficult this is to achieve. Furthermore, the results of our study and the CHANGE study[147] suggest that people with schizophrenia may respond differently to lifestyle interventions from people with other severe mental illness. It is also possible that people with schizophrenia require an intervention that is of greater intensity than other populations to achieve weight loss. In addition to our experience, the INTERvention to Encourage ACTivity, Improve Diet, and Reduce Weight Gain (InterACT) study, which evaluated a healthy-living intervention to control weight in people taking antipsychotic medication after a first episode of psychosis, found no difference in weight change between the intervention and usual care groups.[154]

The results of this trial suggest that interventions that have been shown to be effective in other populations, such as people with diabetes mellitus, are not necessarily effective in people with schizophrenia. Lifestyle programmes for people with schizophrenia should have proven effectiveness and it needs to be recognised that these may need greater resourcing than for other populations.

Chapter 8 Further research

Further analyses of the STEPWISE data set will be undertaken to understand further what predicts a positive response to the intervention. Further health economic analyses within the project will include a comparison of the EQ-5D-5L QALY results with those gained from the SF-36 questionnaire, which generate SF-6D tariffs, which are then used to calculate a QALY. The final analysis will also include a sensitivity analysis, which varies the cost of employment to the minimum wage rate and the cost of informal care to the minimum wage rate and the cost of a home care worker, as mentioned in the methodology.

STEPWISE recruited limited numbers of people with first episode psychosis, and further research is needed into the timing of the intervention to coincide with the often rapid trajectory of weight gain that characterises the early treatment phase for those with a first episode psychosis; moreover, the nature of the intervention may need to reflect the lifestyles and concerns of this typically young population.

Further research into physical health conditions such as diabetes mellitus in mental health should fully explore the optimal approach to ensure that weight loss or QoL changes are sustained over the follow-up period.

Further research should investigate if:

- a more intensive lifestyle management programme with longer periods of maintenance support, complemented by objective measures of weight, diet and exercise, delivered by more experienced facilitators or those from different professional backgrounds, is clinically effective and cost-effective
- a more flexible approach, including both group and one-to-one sessions, is more effective
- a broader approach incorporating the adjustment of antipsychotic treatments and the use of adjunctive pharmacological interventions may be required
- it is possible to overcome the barriers to attendance at lifestyle management programmes
- other formats including family members or carers would be more effective
- lifestyle management programmes should be tailored on the basis of the duration of psychotic illness; for example, interventions for people with first episode psychosis may need to be different from interventions for people with more established disease
- a lifestyle intervention should be combined with specific medication review and/or pharmacological approaches to weight management.

Chapter 9 Conclusions

Despite concerns about the feasibility of undertaking this RCT in people with schizophrenia, we recruited and retained participants successfully in the RCT, indicating the level of interest in this topic among both people with schizophrenia and their mental health care professionals. The RCT showed that the STEPWISE intervention was neither clinically effective nor cost-effective.

Current NICE guidance recommends that mental health-care services should offer a combined healthy eating and physical activity programme to people with severe mental illness, particularly if they are taking antipsychotics.[14] It is clear that many mental health trusts are not implementing this guidance, in part because of a lack of clear evidence about how to do so. When we conceived the STEPWISE trial, we hoped to provide this evidence; however, the results of the trial mean that this is not the case.

Although the process evaluation has identified some of the reasons why the intervention was not delivered as effectively as planned, engagement by staff and participants was good and the sessions were valued highly. This indicates that alternative strategies are needed to overcome the clinical challenge of obesity and overweight in this patient population. A broader perspective that takes account of antipsychotic medication and utilises adjunctive therapies for those who are unable to achieve weight loss through lifestyle modification may be needed. Further research is needed to address these questions.

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The following were involved in the acquisition of data for the work: Daniel Hind, Rebecca Gossage-Worrall, Lizzie Swaby, Marian E Carey, Yvonne Doherty, Janette Barnett and Alison Northern, PIs on behalf of the STEPWISE Research Group.

Publications

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Data-sharing statement

All data requests should be submitted to the corresponding author for consideration. Access to anonymised data may be granted following review.

Patient data

This work uses data provided by patients and collected by the NHS as part of their care and support. Using patient data is vital to improve health and care for everyone. There is huge potential to make better use of information from people's patient records, to understand more about disease, develop new treatments, monitor safety, and plan NHS services. Patient data should be kept safe and secure, to protect everyone's privacy, and it is important that there are safeguards to make sure that they are stored and used responsibly. Everyone should be able to find out about how patient data are used. #datasaveslives You can find out more about the background to this citation here: https://understandingpatientdata.org.uk/data-citation.

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Appendix 1 Semistructured interview guide for participants

TOPIC GUIDE: Participants

Notes: This topic guide is a flexible tool and may be revised as new areas of interest arise during the process of data collection. The wording of questions is for guidance only and can be varied to suit the natural style of the interviewer and the level of understanding of the participant.

Welcome and context-setting

- Introduce yourself
- Remind the participant (and their carer if present), "I work for the University research team, not for the NHS. The content of the interview will not be shared with their health care providers. Nothing you say will affect the care you receive".
- Inform them, "I want to find out what you thought about the STEPWISE programme, so that we can make it better. And I also want to find out how you felt being in the research study so that we can improve research studies in the future."
- "The interview will last approximately an hour"
- Explain that, "to help us with this study, we would like to make a recording of what we all say today, but nobody will be able to identify you from that recording other than me. Is that okay?".
- …There are no right or wrong answers
- You are free to withdraw at any point and you don't have to answer any of the questions if you don't want to.
- Check they are happy to continue and ask if there are any questions.

Questions

1. How did you find the STEPWISE programme?

- Was there anything in particular that you liked about it?
- Was there anything in particular that you didn't like about it?
- How long were the sessions? Was that okay?
- How many sessions did you attend? [Probe: if sessions were missed, why?]
- What did you think of the people who led your group
- Did you feel you got any benefit from the programme? Were there any downsides?
- Did you feel it got the balance right in terms of talking about both diet and physical activity?
- Did you bring somebody with you to the sessions – like a family member? [If no] Do you think that would have been helpful?
- Did the programme meet your needs?
- Did you attend the Booster sessions (if scheduled);
  - Was it useful?
- Did you have any of the one-to-one sessions with your facilitator?
  - [If yes] How often they happen? Was it over the phone? Face-to-face? Some other way?
    Did you find it useful?

    [If no] Would you like to have done so?

2.   Was it easy to fit STEPWISE sessions into your usual routine?

3.   How did you get to the STEPWISE sessions?

- Was it easy to get to the sessions?
- How long did it take?
- [If using a car] What kind of distance did you have to drive, there and back again for each session?
- [If travelling by public transport] Do you mind telling us what you spent getting there and back again for each session?

4.   How do you feel now it's the end of the weekly course?

5.   Would you have preferred it if the STEPWISE sessions had been closer together – for example, every day for four days – rather than spread out over several weeks?

6.   How did you hear about this study?

- How did you feel about being approached to participate in the study?
- How did you feel about a computer deciding whether you were going to go to the STEPWISE sessions or not?

7. We asked you to fill in some questionnaires with the STEPWISE logo on the top, at the beginning of the study and again recently.

- What did you think about the number of questions you were asked?
- Did you have any trouble answering any of the questions?
- We use those questions to find out whether how you are feeling. Did you feel any of the questions were more important than others?

8.   What else should I have asked you?

Thank you for your time

Appendix 2 Semistructured interview guide for health professionals

TOPIC GUIDE: Health Professionals

Notes: This topic guide is a flexible tool and may be revised as new areas of interest arise during the process of data collection. The wording of questions is for guidance only and can be varied to suit the natural style of the interviewer and the level of understanding of the participant.

Section 1. Normalisation Process Theory for implementing interventions (Murray E, BMC Medicine 2010, 8:63)

"I'm going to ask you some questions about the STEPWISE intervention and the service here"

Coherence (meaning and sense-making by professionals):

Is the intervention easy to describe when you're talking to patients and professionals?

Is it clearly distinct from other interventions?

Does it have a clear purpose for patients and professionals?

Do you think patients and professionals have a shared sense of its purpose?

What benefits do you think the intervention will bring; to whom?

Are these benefits likely to be valued?

Does the intervention fit with the overall goals and activity of your organisation?

Cognitive participation (commitment and engagement by professionals)

Do patients and professionals think the STEPWISE programme is a good idea?

Do they see the point of the STEPWISE programme?

Are patients and professionals prepared to invest time, energy and work in it?

Collective action (the work professionals and patients do to make the intervention function)

How has the STEPWISE programme affected your work;

What effect has it had on your consultations and communication with patients and carers?

How does it impact on the way that health professionals in the unit relate to each other?

How compatible is the trial with existing work practices?

Does it seem to be the right thing to be doing?

It is perceived as valid…. as useful?

Who needs to be involved in STEPWISE?

How do we get them informed them and link up with them?

Does rolling out the STEPWISE programme mean health professionals learning new skills or doing things differently?

Do all individuals involved in STEPWISE have the right set of skills?

What impact does the STEPWISE programme have on:

- the division of labour in your unit
- resources
- responsibility between different professional groups?

Does a rigorous protocol for STEPWISE challenge professional autonomy over working practices?

Does the STEPWISE programme impact on case load and allocation of work?

Who has the power to make the STEPWISE programme happen?

Do you think the system wants the STEPWISE programme to happen?

Do we need to and, if so, how can we divert resources to the STEPWISE programme?

Reflexive Monitoring (professionals reflect on or appraise the intervention)

How are users likely to perceive the intervention once it's been on-going for a while?

Is it likely to be perceived as advantageous for patients or staff?

Will it be clear what effects the intervention has had?

Can patients and professionals contribute feedback about study procedures?

Can the intervention procedures be adapted/improved on the basis of experience?

"Thank you, is there anything else you want to say about the STEPWISE programme?"

Section 2. Normalisation Process Theory for optimisation of trial parameters (Murray E, BMC Medicine 2010, 8:63)

"I'm going to ask you some questions about the trial and its procedures now"

"First of all, do you have any general comments about the trial?"

Coherence (meaning and sense-making by professionals):

Is the trial easy to describe when you're talking to patients and professionals?

Is it clearly distinct from other trials?

Does it have a clear purpose for patients and professionals?

Do you think patients and professionals have a shared sense of its purpose?

What benefits do you think the trial will bring; to whom?

Are these benefits likely to be valued by professionals and patients who might take part in the main trial?

Does the trial fit with the overall goals and activity of your organisation?

Cognitive participation (commitment and engagement by professionals)

Do patients and professionals think the trial is a good idea?

Do they see the point of the trial easily?

Are they prepared to invest time, energy and work in it?

Collective action (the work professionals and patients do to make the trial function)

How do the trial procedures affect your work; do they promote or impede it?

What effect has the trial had on your consultations?

Does participation in the trial require extensive training for staff involved?

How compatible is the trial with existing work practices?

What impact does it have on division of labour, resources, power, and responsibility between different professional groups?

Reflexive Monitoring (professionals reflect on or appraise the trial)

How are users likely to perceive the trial once it's been on-going for a while?

Is it likely to be perceived as advantageous for patients or staff?

Will it be clear what effects the study has had?

Can users/staff contribute feedback about study procedures?

Can the study procedures be adapted/ improved on the basis of experience?

"Thank you, have you got any other comments you'd like to make?"

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