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Title: Monitoring oral health of people in Early Intervention for Psychosis teams: The extended Three Shires randomised trial

Running head: monitoring of Oral Health in early intervention for psychosis teams

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Monitoring oral health of people in Early Intervention for Psychosis (EIP) teams: The extended Three Shires randomised trial

Abstract

Background

The British Society for Disability and Oral Health guidelines made recommendations for oral health care for people with mental health problems, including providing oral health advice, support, promotion and education. The effectiveness of interventions based on these guidelines on oral health-related outcomes in mental health service users is untested.

Objective

To acquire basic data on the oral health of people with or at risk of serious mental illness.

To determine the effects of an oral health checklist in routine clinical practice.

Design: Clinician and service user-designed cluster randomised trial.

Settings and Participants

The trial compared a simple form for monitoring oral health care with standard care (no form) for outcomes relevant to service use and dental health behaviour for people with suspected psychosis in Mid and North England. Thirty-five teams were divided into two groups and recruited across 2012-3 with one year follow up.

Results

18 intervention teams returned 882 baseline intervention forms and 274 outcome sheets one year later (31%). Control teams (n=17) returned 366 baseline forms. For the proportion for which data were available at one year we found no significant differences for any outcomes between those allocated to the initial monitoring checklist and people in the control group (Registered with dentist (p=0.44), routine check-up within last year (p= 0.18), owning a

toothbrush (p= 0.99), cleaning teeth twice a day (p=0.68), requiring urgent dental treatment (p=0.11).

Conclusion

This trial provides no clear evidence that Care Co-ordinators (largely nursing staff) using an oral health checklist improves oral health behaviour or oral health state in those thought to be at risk of psychosis or with early psychosis.

Trial ID ISRCTN63382258

Keywords: check-lists, nurses, oral health, psychosis, randomised controlled trial,

Contribution of the Paper:

What is known about this topic:

- The British Society for Disability and Oral Health guidelines made a number of recommendations for oral health care for people with mental health problems, including providing oral health advice, support, promotion and education addressing the oral health needs of clients.
- It is not known if using a checklist to raise awareness of oral health needs has any effect on oral health-related outcomes in mental health service users.

What this paper adds:

- Oral health of those with mental health problems is worse than that of the general population.
- A simple checklist for monitoring oral health may not improve outcomes for this group of service users.
- In mental health services, physical health checklists, including those related to oral health are untested and have potential to waste much practitioner and service user time.
- Future interventions need to be acceptable to service users and nurses who deliver them.

Background

The UK's Five Year Forward View for Mental Health (Mental Health Task Force, 2016) highlights that people with mental health problems have poorer physical health than the general population. Often this group are unable to access the physical healthcare they need and experience unnecessary health inequalities. Given this context the UK's Department of Health (DoH) has produced guidance (Nursing, Midwifery and Allied Health Professions Policy Unit, 2016) to address the physical healthcare, including oral health, of mental health service users. Additionally, a report by the influential Kings Fund (UK) argues there needs to be a stronger focus on integration of physical and mental health (Naylor et al., 2016) and that aspect of integration should lead to development of new models of care for all nurses and other healthcare professionals to address existing health inequalities (Das et al., 2016).

Introduction

Oral health is an important part of physical health and is essential for self-esteem, self-confidence and quality of life (British Society of Disability and Oral Health, 2000; Department of Health, 2005). Oral health is not just about having healthy teeth it is a "standard of health of the oral and related tissues which enables an individual to eat, speak and socialize without active disease, discomfort or embarrassment and which contributes to general well-being"(Department of Health, 2005). Often when a person has serious mental illness their oral health may not be seen as a priority so it can be neglected and deteriorate (British Society of Disability and Oral Health, 2000). Also, oral health problems may not be detected by mental health professionals (Hede, 1995) and, to compound the matter, many dentists shy away from treating people with psychosis (Klinge, 1979; ter Horst, 1992).

Surveys that describe oral health of people with serious mental illness have concluded that oral health is poor and significantly worse than the general population (Hede, 1995; Klinge,

1979; Mirza et al., 2001; Tang et al., 2004; ter Horst, 1992; Zusman et al., 2010) (please see Supplemental File appendix 1). A systematic review of advanced dental disease found that people with mental illness were 3.4 times more likely to have lost teeth than the general population and had higher rates of decayed, missing or filled teeth (Kisely et al., 2011). Amongst other problems, medication prescribed for serious mental illness can cause a lack of saliva, or be dispensed in sugar syrup which can lead to caries (Cormac and Jenkins, 1999; Friedlander and Marder, 2002). Hypersalivation is also a side effect of treatment with clozapine. There are also neurological effects of first-generation antipsychotics (dystonia, dyskinesia) and second-generation antipsychotics induce more metabolic side effects like obesity or diabetes and these are linked to periodontal diseases (Fratto and Manzon, 2014; Matos Santana et al., 2017; Vancampfort et al., 2015). A meta-analysis of fifty seven studies looking at the prevalence of suboptimal oral health of people with mental illness, found a suboptimal oral health prevalence of 61% as well as highlighting the need for oral health training for mental health professionals (Matevosyan, 2010).

The British guidelines published in 2000 made a number of recommendations for oral health care for people with mental health problems, including providing oral health advice, support, promotion and education addressing the oral health needs of clients (British Society of Disability and Oral Health, 2000). Providing advice and education (diet advice for reducing frequency of sugar intake and tooth brushing advice on correct techniques and duration) are not sufficient to ensure improvement in oral health. It is imperative that compliance and stability in oral health following education and advice is monitored and reinforced as necessary until stabilisation is achieved (Department of Health, 2005). A Cochrane review investigating *the effects* of such approaches found no relevant randomised trials comparing an oral health *advice* or *monitoring* intervention with standard care for people with serious mental illness (Khokhar et al., 2011). It was hoped that such monitoring, partly designed to

precipitate help and advice where needed, may have practical measurable benefits (Naylor et al., 2016). It is equally possible that such activity has no discernible effect.

Objectives

To acquire basic data on the oral health of people with or at risk of serious mental illness.

To determine the effects of oral health advice or monitoring in routine clinical practice. Specifically we wished to examine whether dental monitoring with minimal dental awareness training leads to a clinically significant difference in oral health behaviour of people with serious mental illness.

Methods

Detailed methods are published elsewhere (Jones et al., 2013) but described briefly in the sections below.

The study:

Design

The simple trial design and intervention were drawn up after extensive consultation with local clinicians and service users so the study was acceptable with minimal disruption to standard care.

Setting

The trial was conducted as part of standard care provided by the Early Intervention in Psychosis (EIP) teams, first in Nottinghamshire, Derbyshire and Lincolnshire (UK), and then in other teams across northern England (Bradford, Doncaster, Durham, Leeds, Northumberland, Wakefield). The teams cover a mixture of urban and rural areas with a diverse population. The multidisciplinary EIP out-patient teams provide intensive treatment

and support to people with a first experience of symptoms such as hearing voices or those who develop unusual beliefs which may indicate the onset of psychosis. The teams have a Senior Manager overseeing the Care Co-ordinators (mostly nursing staff) who are the main contact person for service users throughout their involvement with the service; it was the Care Co-ordinators who were delivering the intervention in this trial to their service users. This work was part of the portfolio of work of the UK's East Midlands' Collaboration for Leadership in Applied Health Research and Care (CLAHRC) diffusing best health practice, in this case, simultaneous with its evaluation. Team recruitment was at first targeted to the three Shires (Nottinghamshire, Derbyshire and Lincolnshire) and then spread by word of mouth. We undertook no recruitment drive beyond the initial three Shires.

Sample size

Because no previous trials existed (Khokhar et al., 2011) power calculations were difficult. We also had no estimate of Intraclass correlation co-efficient (ICC) to help take clustering into account. Non-cluster sample size needed to detect an absolute difference of 15% in the proportion of 'dental care not deteriorated' was calculated (using Stata 10, alpha=0.05, power = 0.80; design effect 1.9). Samples size estimates, for participants within teams, varied from just over 400 (20% vs 5%, adjusted for 20% loss to follow up) to nearly 900 (50% vs 35%) (Jones et al., 2013).

Procedure

Before teams were randomised, all EIP Managers were given information sheets and asked to sign a consent form providing permission for their team to be involved. We collected demographic information including team location, number of Care Co-ordinators within the team, size of caseloads and distance to dental services from the team base. The trial team did

not have access to identifiable NHS data. Recruitment of teams (n=35) took place across 2012-3 and follow up was for one year.

Randomisation

This was a pragmatic, open, cluster randomised controlled trial with matching on location and size of team. The Nottingham Clinical Trials Unit (NCTU) created a randomisation programme, worked with an anonymised list, to randomise the teams (block randomised by County, stratified by size of team).

Participants

EIP teams through consent of their Managers and the trial team Care Co-coordinators who, in turn, recruited service users. Care Co-ordinators were informed of all aspects concerning participation in the trial.

Inclusion Criteria

Initially any EIP team and any service users under the care of a Care-Coordinator in one of these teams, who was aged 18 years or above.

Exclusion Criteria

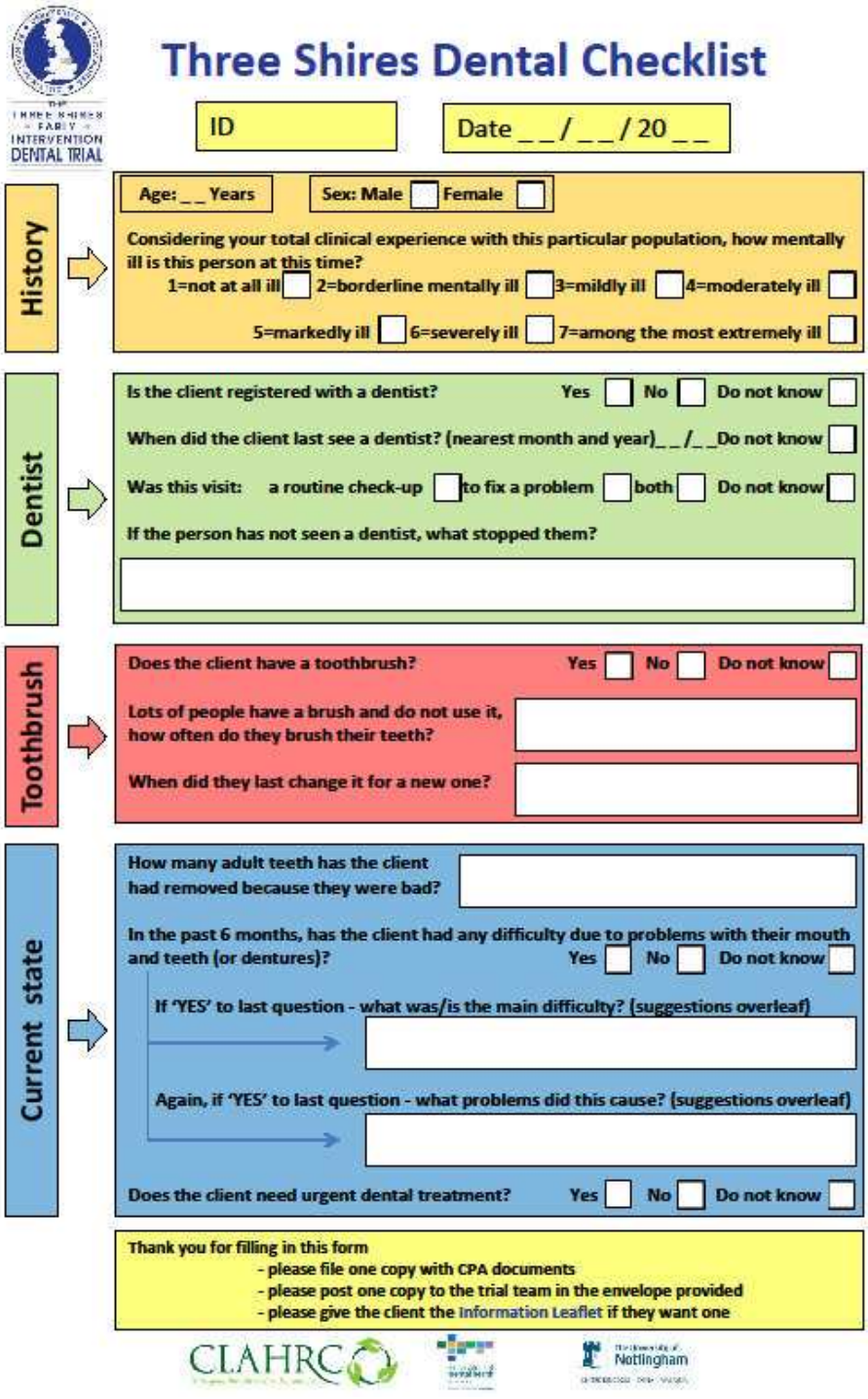
Any overall EIP team which did not want to take part, or any service user or individual Care Co-ordinator within a team who did not wish to take part.

Intervention group

After randomisation, EIP teams allocated to receive the dental intervention were approached by the trial team to arrange the dental awareness training (Jones et al., 2013). Information sheets were given out to Care Co-ordinators and additional consent forms signed. This fitted within the usual multidisciplinary team meetings but took around 30 minutes. A manual ensured consistency. The training briefly covered the agreement of the importance of oral

health care in this group, encouragement of awareness of this aspect of care, aims and background of the trial, how to complete the checklist, service user ID number allocation, how to return completed checklists to the trial team and discussion about what to do in certain situations regarding adverse events (Jones et al., 2013). We did not expect any adverse *effect* of the lists but left recording and definition of anything adverse (relapse, self-harm, hostile event) open to the discretion of the Care Co-ordinator. The dental checklist (see Figure 1) was adapted from the British Society for Disability and Oral Health (BSDH) guidelines (British Society of Disability and Oral Health, 2000) and carried, embedded within it, the Clinical Global Impression (CGI, (Guy, 1976)) categorical checklist (Figure 1, History). The Care Co-ordinators were encouraged to use the checklist for all their service users at their earliest convenience. These experienced clinicians – mostly nurses - were given no additional training beyond the initial awareness-raising meeting but this simple approach is in keeping with the premise for using the CGI (Guy, 1976). The checklist was printed on carbon-less copy paper, one copy of the dental checklist was kept in the service users' notes and one returned in pre-paid envelopes to the trial team.

Figure 1. The checklist



Control Group

EIP teams allocated to the control group continued to deliver standard care for 12 months. This involved Care Co-ordinators providing regular, minimally intrusive, informal monitoring of mental, physical and social state and concordance with treatments. This did not

involve either the awareness-raising minimal dental health training, or the use of the specific tailored checklist. However, one year after the intervention group the Care Co-ordinators in the control then received the dental awareness training and were asked to use the dental checklist, for those who they had been caring for within the team one year earlier, following the same procedure as the intervention group. The checklist was designed also to act as the outcomes acquisition form. Care Co-ordinators in control teams were given information sheets and asked to sign consent forms (Jones et al., 2013).

Follow up

The trial team prompted the intervention group Care Co-ordinators for the 12 month follow up where dental checklists were to be completed again for all service users – the intervention checklist doubling as the outcome form. In keeping with the request of the Scientific Committee of CLAHRC we were to randomly select a 100 service users (and their Care Co-ordinators) to be asked if contact from the trial team is acceptable regarding gathering additional data via the Oral Impacts on Daily Performance (OIDP) (Adulyanon et al., 1996) measure – widely validated including for people with mental health issues - as well as for collecting detailed data from their dentist.

Outcomes

All outcomes were stated a priori (Jones et al., 2013).

Primary

Number of service users who have visited a dentist within 12 months of exposure to the checklist.

Secondary

Registered with dentist, routine check-up within last 12 months, owning a toothbrush, cleaning teeth twice a day, non-routine visit to a dentist in last year, replacing existing

toothbrush within the last six months, problems with mouth and teeth, and Oral Impacts on Daily Performance (OIDP) checklist.

Data analysis

This was a cluster randomised controlled trial. We anticipated 600-800 dental checklists to be completed during the trial. The analysis followed intention-to-treat principles. Multilevel modelling was used to explore whether the intervention has made a clinically significant difference to the data collected from the intervention teams. Intercept only multilevel modelling was first performed to investigate variability of each outcome measures at the location level and team level. No statistically significant location and team level variance was found therefore the treatment effect was quantified by single level regression modelling with robust standard error adjusting trivial location effects. Data were entered into a password protected database with an audit trail. MLwiN software was used to perform multilevel modelling, STATA 14 was used to perform other relevant analysis. It was anticipated that service users would leave the study early, but we planned to follow up as many as possible. The treatment influence on 'missingness' was explored using multilevel logistics regression modelling with location as level 3 unit and treatment team as level 2 unit. The result was used to inform missing value imputation. With assuming data missed at random, a multiple imputation method was performed to impute missing values. Treatment effects were quantified with MI dataset. However, as sensitivity analysis, we also ran relevant modelling with observed dataset. The results of MI dataset and observed dataset are virtually identical. STATA 14 was used to impute' missingness'.

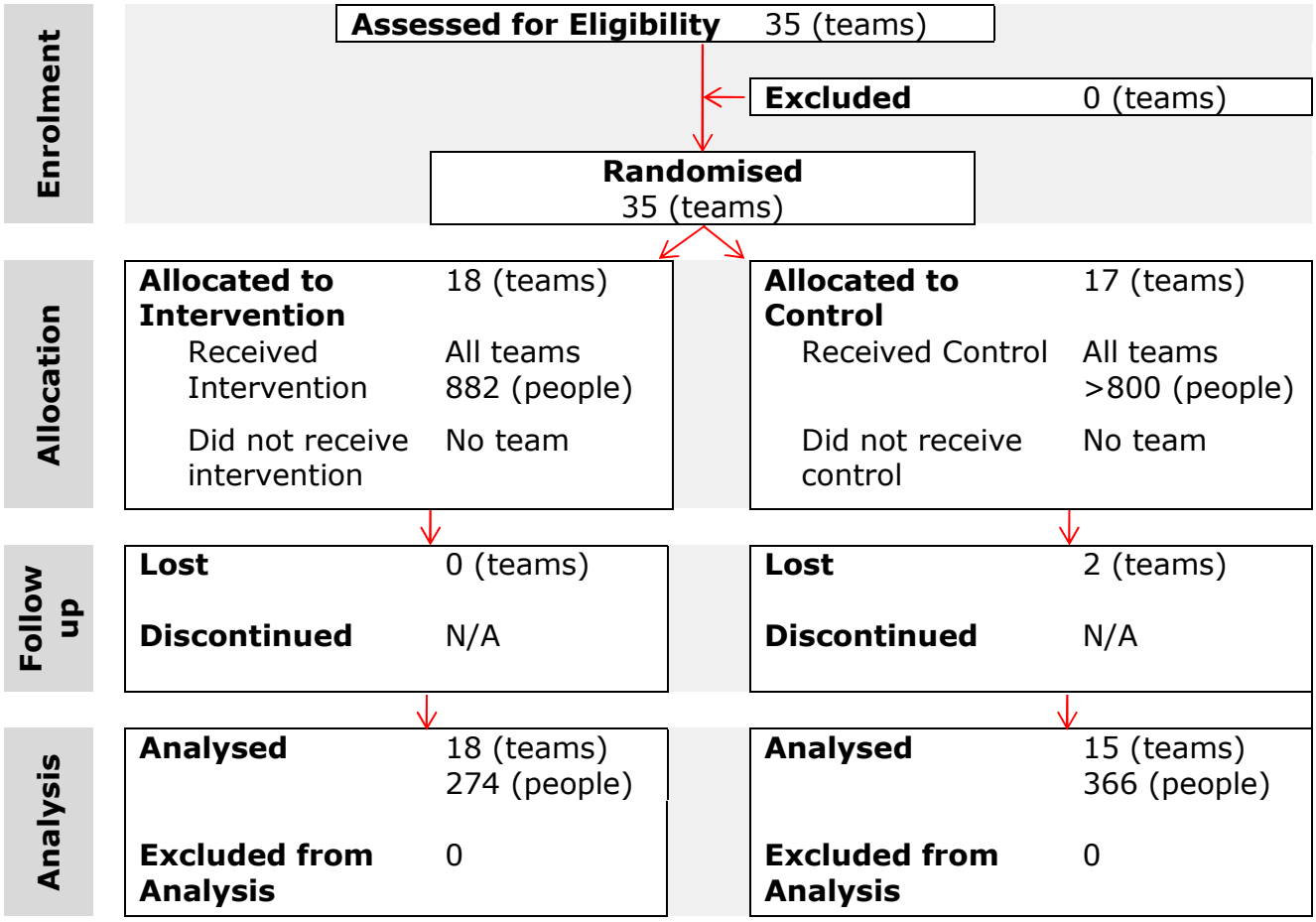
Ethical considerations

The trial received support from the East Midlands Nottingham Research Ethics Committee (REC) (REC reference 11/EM/0205) and from the Nottinghamshire, Derbyshire and Lincolnshire National Health Service (NHS) Research & Development (R&D) departments.

Results

Recruitment of teams (n=35) took place across 2012-3 and follow up was for one year. The intervention teams returned 882 baseline intervention forms and the matching of control group allowed estimation of numbers of clients within the control teams to be broadly similar (figure 2). The intervention teams returned 274 outcome sheets one year after their initial baseline form. Two control teams returned no forms, and we gained 366 from the remaining 15 (figure 2). Not all returned forms were complete. In total we gained baseline data from 1248 people (882 intervention group, 366 controls) (figure 2).

Figure 2. CONSORT diagram



a. Overall demographics and clinical state

The average age was 26 years (SD 6, median 25, range 15-56). Seventy percent of people were under 30 years of age. Around two thirds of the sample was male. Most of this group were rated on the Clinical Global Impression (CGI) (Guy, 1976). We classified CGI data into two main categories (mildly unwell, and moderate to severely unwell). Over two thirds of people were categorised as the former (Table 1).

Table 1. Overall demographics and clinical state

Age			**Gender**			**Severity of illness**		
Groupings	N	%	Category	N	%	Category	N	%
<20	105	10%	Male	726	66%	Mildly unwell/ not really unwell	681	68%
20-24	355	34%	Female	369	34%	Moderate to severely unwell	318	32%
25-29	266	26%						
30-34	210	20%						
35-39	72	7%						
40-44	17	2%						
45-49	5	0%						
50 +	4	0%						
Totals	**1034**	**100%**		**1095**	**100%**		**999**	**100%**
Missing	214	17%		153	12%		249	20%

b. Background dental history

As part of the background history the 1248 people were asked about their oral health behaviour and problems (Table 2).

Table 2. Background dental history

a. The Dentist						
Does the person currently feel they are registered with a dentist?	Yes	No	Do not know		**Total**	Missing
	770 70%	284 26%	49 4%		**1103 100%**	145 21%
Last visited dentist	in last 2 years	2-3 years	3-4 years	over 4 years		
	603 80%	43 6%	19 3%	82 11%	**747 100%**	501 40%
Reason for visit	routine check up	to fix a problem	do not know			
	584 60%	295 30%	102 10%		**981 100%**	267 21%
b. Current basic oral hygiene						
Owning a toothbrush	Yes	No	Do not know			
	1080 98%	11 1%	11 1%		**1102 100%**	146 12%
How often do you brush your teeth?	1 per day / few times week	Once or twice a day	2-3 times a day	Other		
	421 40%	42 4%	536 50%	69 6%	**1068 100%**	180 14%
c. Past dental history						
In the last 6/12 have there been any dental/oral difficulties/problems?	Yes	No	Do not know			
	354 33%	712 66%	13 1%		**1079 100%**	169 14%
Teeth removed?	Zero	1-2	3-5	>5		
	672 62%	227 21%	135 12%	53 6%	**1087 100%**	161 13%
d. Current dental need						
Does the person currently need urgent treatment?	Yes	No	Do not know			
	73 7%	969 90%	33 3%		**1075 100%**	173 14%

The majority of the sample were registered with a dentist (70%) and had been to that dentist within the last 2 years (80%). We asked “if the person has not seen a dentist, what stopped them?” After gaining advice from a Public Health dentist these free text answers were collated. With dental advice we also categorised the free text ‘main dental problem’ (Table 3). As with the general population, NHS Primary care dentists are the first port of call for oral

health provision of people with psychosis. Access is no different to other parts of the country and dentists are required to provide equitable care to all irrespective of underlying mental health problems. However, if some patients with severe psychosis display signs of agitation such that they are unable to stay still in the dental chair to allow treatment to be undertaken, the treating primary care dentist will have the option to initiate a referral to secondary care where the patient is likely to be seen by a special care dentist (a branch of dentistry that deals with patients with special needs) where treatment can be undertaken under sedation or general anaesthesia as required. NHS dental treatment charges are payable in primary care unless the patient receives the following: Disability living allowance and incapacity benefit, Income Support, income-based Jobseeker's Allowance, income-related Employment and Support Allowance or Pension Credit guarantee credit or Universal credit. Treatment in NHS secondary care does not incur a charge.

The normative data of the 2009 Adult Dental Health Survey (ADHS) reports that 58% of their sample of over 17 thousand people had tried to make an NHS dental appointment in the previous three years (Health and Social Care Information Centre, 2011). In our sample more - 86% - had visited a dentist in the last 3 years, suggesting they have both a higher dental need and access than a normative population (Health and Social Care Information Centre, 2011). In our sample half cleaned their teeth 2 or 3 times a day – this is significantly worse than the general population (Table 4).

Table 3. Reasons for not seeing dentist and main difficulty

Reason	N	%	95% CI	**Main problem**	N	%	95% CI
Apathy	18	7	4-10	Pain	85	26	21-31
Cost	13	5	3-8	Gums	67	20	16-25
Dental avoidance	46	17	13-23	Chipped/ Broken	46	14	10-18
Mental health	7	3	1-5	Fillings	38	11	8-15
No need	59	22	17-27	Decay	30	9	6-13
Not registered	55	21	16-26	Other	25	8	5-11
Other	44	17	12-22	Wisdom Teeth	19	6	4-9
Unsure	9	3	2-6	Sensitivity	17	5	3-8
(blank)	14	5	3-9	Colour	3	1	0-2
				Brace/ Orthodontic	3	1	0-2
Total	**265**	**100**			**333**	**100**	

Table 4. The UK EIP Team sample versus similar general population values

	Current sample	ADHS 2009	
	(n= up to 1248)	All adults (n= 17849)	Age specific data
Cleaning teeth 2 or more times a day	50% (95% CI 47-53)	75% (95% CI 74-76)	16-24: 72% 25-34: 76%
Reason for dental checkup	Routine checkup: 50%	Regular checkup: 61%	16-24: 51% 25-34: 44%
		Occasional checkup: 10%	16-24: 14% 25-34: 14%
	To fix a problem: 25%	Only when having trouble: 27%	16-24: 33% 25-34: 38%
	Do not know: 9%	Never been to the dentist: 2%	16-24: 2% 25-34: 3%
Requiring urgent treatment	6%	9%	16-24: 9% 25-34: 10%
Owning a toothbrush	92%	100%	16-24: 54% 25-34: 41%
Tried to make an appointment in the last 3 years	Yes: 86%	Yes: 58% No: 42%	16-24: Yes: 57% No: 43% 25-34: Yes: 60% No: 40%
Registered with a dentist	Yes: 65% No: 24%	No data	

In our sample of young people around 40% had had teeth removed with 6% having more than five extracted. The ADHS survey 2009 reports that 86% of their sample had "functional dentition" (≥21 teeth). Although our sample was not asked exact numbers of teeth present, our findings do not seem radically different from the ADHS 'norm'.

Follow up

Overall, within the intervention group, the percentage with returns of the second checklist after one year was 274/882 (31%). For the control group we gained 366 baseline/follow up sheets. For this group we cannot be sure of the denominator as this was not supplied and we could not access the number of clients in each team on day one of the trial. Each team and district being matched, we have no reason not to assume control team numbers were also over 800 people. Age, gender, mental state were not different for those who had a final follow up

checklist returned in the intervention group, and people allocated to the control group. This study was designed as a cluster trial with the concern that there may be contamination between carers within teams. We therefore, randomised at team level. There was, however, no indication of any interaction between shire or between team, as multilevel modelling, aiming to explore shire and team level variability, did not show the variance of outcomes at shire level and team level were statistically significant.

Between group differences

For people for whom we gained follow up data at one year we found no differences for any outcomes between those allocated to the initial monitoring checklist year and people in the control group. There was no evidence from these data that using a checklist helps people ensure that those thought to be at risk of psychosis or with early psychosis have their oral health behaviour or state improved (Table 5). There were no serious unexpected events.

Table 5. Between group differences

		Intervention		Control	B* (95%CI)
		Baseline	Follow up	Baseline	
Registered with dentist (n)	Yes	560	184	223	.13 (-.20, .45), p=.44
	No	202	60	85	(reference)
	Do not know	35	13	17	.24 (-.47, .95), p=.49
Routine check-up within last year	routine check up	424	123	172	-.20 (-.51, .10), p=.18
	to fix a problem	209	78	89	(reference)
	Do not know	80	35	25	.41 (-.16, .98), p=.16
Owning a toothbrush	Yes	776	247	324	-.01 (-2.14,2.12), p=.99
	No	10	1	1	(reference)
	Do not know	9	1	2	-.11 (-2.48, 2.56), p=.92
Cleaning teeth twice a day	<2/day	353	57	146	(reference)
	~2+/day	417	62	172	-.09 (-.57, .37), p=.68
Requiring urgent dental treatment	Yes	51	28	24	.49 (-.11, 1.10), p=.11
	No	703	207	284	(reference)
	Do not know	21	5	12	-.51 (-1.62, .61), p=.37

*** log (OR) for Cleaning teeth twice a day and Log (Relative Risk Ratio) for other outcomes**

Because of limited funding and restrictions in what staff would do, no prospective data were collected with regards to specific health economic outcomes such as quality of life measures and OIDP. In addition, due to changes within EIP teams the planning, formulation, training and implementation of the dental awareness training as well as staff contact time for completion of checklists was difficult to estimate. Calculation of cost-effectiveness would be error-prone in such circumstances and is liable to be highly inaccurate.

Discussion

The demographics of the sample reflect what would be expected in most early intervention teams (Purcell et al., 2014). Around a quarter of our sample felt they were not registered with a dentist. We are unsure of how this compares with the wider population but think this is likely to indicate early signs of disengagement with dental services. Comparison with UK normative data of the 2009 Adult Dental Health Survey (ADHS) highlights how more of this sample had visited a dentist in the preceding 3 years and that around half cleaned their teeth 2 or 3 times a day was also significantly worse than the general population. In this trial some other indicators of oral health were not that different from the ADHS norm (for example, overall dentition). There is some evidence, however, that the overall oral health care for this sample from EIP teams is not as good as the general population. It may be that not enough time has passed for this relatively young sample for more concrete indicators (overall dentition) to show up differences.

The EIP sample seems to have very standard reasons for not seeing the dentist. Few reasons are clearly attributable to mental illness. ‘Dental avoidance’ was cited by 17%. Some degree of dental fear, however, is common generally and our figure concurs with that in wider sample in England (15% of under 35s) (Armfield et al., 2007; Kleinknecht et al., 1984).

Implications for nursing practice, research and education

The most common dental diseases leading to poor oral health are dental caries and periodontal disease are preventable. Care Co-ordinators may need to be reminded of simple preventative measures (use of sugar-free medication, restricting intake of sugary foods to mealtimes, appropriate tooth brushing techniques, regular dental visits) to share with receptive service users and we would see this as the point of a checklist designed to dovetail into routine care. Further qualitative research is needed to understand the barriers to managing oral health needs of those with mental illnesses and any intervention designed can address these barriers. It is likely that the neglect of self-care in persons with severe mental illnesses may be influenced predominantly by the symptoms of their mental illnesses, such as a lack of concern for personal health and a lack of motivation. In other words, the mechanisms of this involvement and finding out what meaning persons with severe mental illness associate with oral health in the context of their mental illness symptoms warrant investigation in the future. This research should involve views of not only the service users but also carers (family, nurses) and dental practitioners.

Whilst the trial did not demonstrate improvement of oral health with the use of simple nurse-led checklists, it did highlight the oral health needs of those with mental illness and showed that the oral health of people with serious mental illness is poor and significantly worse than the general population. This concurs with previous research (Hede, 1995; Klinge, 1979; Mirza et al., 2001; Tang et al., 2004; ter Horst, 1992; Zusman et al., 2010). Health care practitioners closest to the service user (often nursing staff) should be aware of this issue. It is feasible that a simple checklist could help awareness, be integrated into routine care and have beneficial effects but this randomised trial had such attrition across one year that no firm conclusions on the efficacy of a list should be drawn. Often such checklists are mandatory for health care professionals dealing with this service user group and we remain unsure if they

are of any practical value. The window this trial gives into turnover of nursing staff across a limited follow up is valuable in highlighting the problems with continuity of care, and research embedded in routine care, across any but short periods of follow up. In addition, because of limited funding and restrictions in what staff would do, no prospective data were collected with regards to specific health economic outcomes such as quality of life measures and OIDP and further trials in this area need to integrate and assess quality of life implications of poor oral health in this group.

Implications for research

Recruitment of teams was not difficult. Teams saw the purpose of the trial, liked the design but also the potential reward of being involved. Pragmatic bottom-up designed trials are attractive even to stretched current services. The initial enthusiasm, however, could not be sustained by the Trial Team and with drift of staff and time and delays the energy was dissipated and subsequent response rate poor. There were clearly difficulties in the acquisition of final data with only 31% follow up of those initially recruited. We think this is for a variety of reasons. The open pragmatic and inclusive design of the study was both strength and a weakness. All stakeholders had been involved in the design with the exception of the Scientific Committee of the funders who were presented with a design *fait accompli* to which the committee did not relate. Truly pragmatic designs (Adams, 2013; Thorpe et al., 2009) in mental health trials are not common (Tosh et al., 2011) and the Scientific Committee made the study more complex than the stakeholders wanted it to be and, perhaps, more than it had the capacity to be. In addition, top-down changes served to accomplish two other things. First, clinicians and service users who had designed the study began to feel the [familiar] lack of ownership and less buy-in in its conduct. Second, with the considerable enforced time delay a window of opportunity for this study was closing. Every day from the design

consultation meetings meant more staff who had enthusiastically owned the study were lost to its conduct.

We underestimated the turnover of staff in the UK's NHS EIP teams. This combined with morale issues and lack of research culture or hostility to research made the job of the person employed for the Three Shires part of the study very difficult. The idea had to be reintroduced to new staff with ever-less 'ownership' of the trial. Here the pragmatic design may have been the weakness. With staff unfamiliar to the question-setting process, and the buy-in that comes with self-design the simplicity of the study allows it to not be a priority to a busy workforce. Here an explanatory design with the complexity and investment may have garnered more energy from the dissipating workforce.

Conclusions

We found no evidence that a reminder checklist had any effect at the end of one year follow up. Our trial had poor follow up and it is possible that this finding is true or false. If true, and generalizable across different health checklists, there remains the possibility of enormous waste of resource in asking health care professionals to undertake such checklists for purposes of audit rather than for any valuable clinical outcome. It is, however, also possible that a real effect was missed by our study. Because of the likely continuing investment in the low-grade health monitoring across very large populations of people, and because of how this study indicates the feasibility of randomisation in this area within routine care, we still feel that an appropriately-resourced and supported randomised trial is possible and needed. Future interventions need to be acceptable to service users and clinicians who deliver them and target the wide spectrum of mental health conditions that present with varying levels disability.

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Declaration of Interest

No authors have any pecuniary interest in the results of this work. There are no conflicts of interest.

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