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# Title

Working with Insulin, Carbohydrates, Ketones and Exercise to Manage Diabetes (WICKED): Evaluation of a self-management course for young people with type 1 diabetes

What's new? (100/100 words)

- Self-management courses have been established for children and adults with diabetes; however, these may not be appropriate for young people (16-24 y) who face unique developmental challenges.
- The WICKED self-management course seeks to improve young people's control of their diabetes through increasing knowledge, self-efficacy and self-management behaviours, while acknowledging their specific needs and challenges.
- The course was developed and delivered in Sheffield before being evaluated in two other centres with different models of transition care.
- The WICKED course was found to increase self-report knowledge, self-efficacy and selfmanagement behaviours.
- Statistically significant reductions in HbA1c were observed at 6 and 12 months follow-up.

#### Abstract (250/250 words)

*Aims*. To evaluate a five-day self-management education course for young people with type 1 diabetes and assess its effects on knowledge, self-efficacy, beliefs, distress, self-management behaviours and HbA1c.

*Methods*. This is an evaluation of a structured education course. Young people (aged 16-24) with type 1 diabetes were recruited from three diabetes centres. In the first centre, participants completed self-report measures of knowledge, self-efficacy, positive and negative outcome expectancies, and hypoglycaemic worries at baseline (N=47) and the end of the course (N=42). In two additional centres, participants completed these and other measures assessing self-management behaviours, cognitive adaptation to diabetes and diabetes distress at baseline (N=32), the end of the course (N=27) and three-month follow-up (N = 27). HbA1c levels were recorded at baseline (N=79), six (N=77) and 12 (N=65) months.

*Results.* There were statistically significant increases in self-report knowledge, self-efficacy, positive outcome expectancies, and self-management behaviours, and a statistically significant decrease in negative outcome expectances, between baseline and the end of the course. There were also statistically significant increases in self-report knowledge, self-efficacy, self-management behaviours and cognitive adaptation to diabetes between baseline and 3-month follow-up. Compared with baseline, HbA1c levels decreased by 5.44 mmol/mol (0.48%) at 6 months (P=0.019, SD=19.93), and by 5.98 mmol/mol (0.54%) at 12 months (P=0.043, SD=23.32).

*Discussion*. The results indicate the potential benefits of a self-management course designed to address developmental needs and challenges faced by young people with type 1 diabetes. Further studies with larger numbers and appropriate controls are required to confirm these initial findings.

Working with Insulin, Carbohydrates, Ketones and Exercise to Manage Diabetes (WICKED): Evaluation of a self-management course for young people with type 1 diabetes

# Introduction

Young people with type 1 diabetes in the UK face challenges where they struggle to achieve recommended HbA1c targets. Moreover, some of these young people already have microvascular complications and are lost to follow-up during the transition from paediatric to adult care [1, 2]. The introduction of the Paediatric Diabetes Best Practice Tariff (BPT) in England in 2012 recognised the importance of this age group and the need for further intervention [3]. The Tariff is provided to those centres which meet 13 Standards, one of which is the provision of structured education. In addition, NICE guidelines for children and young people with diabetes have included structured education. The 'Taking Control' campaign by Diabetes UK sees the lack of provision of diabetes education as the "big missed opportunity in diabetes care" as it is estimated that, on average, people with diabetes spend only three hours a year with health care professionals, spending the rest of the time managing their condition alone [4, 5, 6]. Moreover, it is critically important to provide structured education to those diagnosed as young children since their parents will have received most of any educational input.

Structured education courses are currently available in the UK for both adults and children with diabetes. The DAFNE (Dose Adjustment For Normal Eating) course, delivered over five days teaches adults with type 1 diabetes to separate delivery of basal and bolus insulin, thereby promoting dietary freedom and improving blood glucose control [7]. People with type 1 diabetes are taught to count carbohydrates and use mealtime ratios to adjust quick acting insulin to carbohydrate consumed, based on pre-meal blood glucose measurements and anticipated physical activity [8]. DAFNE leads to clinically significant falls in HbA1c, reduces risk of both severe

hypoglycaemia and diabetic ketoacidosis and sustained improvements in health-related quality of life (HRQoL) making it highly cost-effective [3, 9, 10]. One trial reported clinically relevant reductions in HbA1c for up to two years [REPOSE][11]. A related programme (KICk-OFF) [12] has been developed for children (11-16 years) and has demonstrated a sustained improvement in HRQoL, but not glycaemic control [13].

Despite these encouraging findings, courses developed specifically for adults or children may not be appropriate for young people (16-24). Information about how to manage diabetes may not adequately address problems specific to young people. Emerging adulthood is a distinct developmental period between adolescence and adulthood that can span from a person's late teens until their late twenties. It is typically a time of great change when young people are often dealing with many changes in relationships, geography and education/occupation, which means that diabetes is often not a priority or that they need to adapt their diabetes management to novel situations. Young people are therefore likely to have distinct needs that are not met by existing structured education courses [14, 15, 16, 17]. Existing courses for children do not encourage selfmanagement independently from parents, whilst adult courses are designed to provide more structured self-management advice. Young adults fall between these two educational models. Although they require the basic knowledge about glucose control, this knowledge needs to be tailored to their individual circumstances and preferences, facilitating greater independence from parents.

These views were clearly expressed by young people when attending a DAFNE course designed for adults [7, 18] and highlighted a need for the development of an age-appropriate structured self-management education course to bridge the gap between courses developed for children [13] and adults [18]. WICKED (Working with Insulin, Carbs, Ketones and Exercise to manage Diabetes) was developed to fill this gap [19].

#### The current study

The current study was an evaluation of the course, assessing its impact on a range of biomedical, psychological and behavioural outcomes. The course was first delivered in Sheffield where it was developed. Two additional centres (Harrogate, Leeds) were then recruited to assess whether the intervention could also be delivered successfully elsewhere.

## Methods

# Participants and procedure

The course was initially designed by the CI and specialist nurses working at the first pilot centre and delivered to test the intervention effectiveness. The success of the course in both achieving positive clinical outcomes and enthusiasm and support of the staff delivering the course led to recruitment of two additional centres, to test the replicability of the intervention in different settings. The intervention was the same across all three centres, except that local staff were trained to deliver the course. They were observed and mentored by experienced trainers who were involved in the course design, and able to translate the course philosophy to the staff at the two new centres.

Participants were young people (aged 16-24) with type 1 diabetes in northern England. There is substantial variability in how services for type 1 diabetes are delivered in the UK. The three centres participating in the study reflect this diversity. In the pilot centre (Sheffield), young people transition to the adult service by their sixteenth birthday. Young people then attend a clinic between the ages of 16 and 21 and a young adult clinic between the ages of 21 and 25 years. In the first extended pilot centre (Harrogate), young people attend a young person's clinic

between the ages of 16 to 25. In the second extended pilot centre (Leeds), the transition service includes individuals aged 16-19 years who subsequently move to the young adult clinic, which covers those aged 19-25 years.

In each centre, potential participants were sent a letter from their named consultant with details of the course and the study (Sheffield 120, Harrogate 90, Leeds 160). The baseline sample was 79, giving a response rate of 21.4%. Clinic staff then approached young people at their next clinic appointment to discuss involvement. In the pilot centre, self-report data were collected at the start (baseline) and the end of the course, whereas in the two extended pilot centres, self-report data were also collected at three-months. HbA1c values were obtained from medical records in each centre at baseline and after six and 12 months.

Participants gave written consent and ethical approval for the study was obtained from East Midlands Nottingham NRES Committee (ref.: 15/EM/0065).

## WICKED course

WICKED is a five-day self-management course for young people with Type 1 diabetes (Figure 1) [19]. To facilitate attendance, the courses are run in school holidays or half-term breaks over five consecutive days. A mixture of insulin regimens is allowed, and participants are encouraged to attend regardless of length of time since diagnosis. The course begins with a recap of Type 1 diabetes and carbohydrate counting, progresses to key skills such as sick day rules and dealing with hypos and finishes with social issues on the final two days. Young people choose their own blood glucose targets following group discussions where the purpose of targets and the national guidance is provided. They are encouraged to record their glucose values on a chart, shared by the group as they learn to recognise patterns and potential solutions. Participants generally work

in a group throughout the week but each participant has an educator who acts as a key worker with whom they have some one-to-one sessions to incorporate their individual needs. The scheme of work is flexible to the concerns and interests of the specific group and while key skills are always included, these dictate the latter days (for example how much time is spent on exercise, alcohol, travel, etc.). By the end of the week, young people should be able to identify patterns in glycaemic control, adjust for snacks and exercise, correct a high glucose, treat a hypo and understand the impact of type 1 diabetes on social activities such as drinking alcohol and travel.

### Pilot and Extended Pilot

The WICKED course was initially delivered in Sheffield by diabetes specialist nurses and dietitians working in the diabetes service. The delivery of the course in this centre gave staff from the two extended pilot centres (Harrogate, Leeds) the opportunity to observe a WICKED course in full. When the courses were delivered in the additional centres, an educator from the pilot centre acted as co-educator for the first course that they ran and was present for the other courses offering support when the local educators needed it. Six courses were completed in the pilot centre between May 2012 and February 2013 that were attended by between 7 and 10 young people (Median=7.5). Six further courses were completed in the two extended pilot centres between July 2015 and January 2016 that were attended by between 4 and 7 young people (Median=5). Participants only attended one course.

#### Descriptive measures

Measures of age, gender and ethnicity were taken from medical records, along with clinical details (e.g., length of diagnosis, regimen).

### Outcome measures

*HbA1c* scores were taken from medical records at baseline and after six and 12 months. Participants from the pilot centre also completed a range of self-report measures at the start and the end of the course, but not at three months follow-up. Participants from two centres recruited for the extended pilot also completed the self-report measures again at three months.

*Knowledge* about diabetes was assessed with a 17-item measure developed by the research team who included diabetes consultants and diabetes specialist nurses. Participants were asked to indicate how much they felt they understood 17 topics covered in the WICKED course (e.g., which foods contain carbohydrate, how the body uses insulin) on 5-point response scales ranging from 1 (I know almost nothing) to 5 (I know everything I need to know). Scores on the items were averaged with higher scores indicating greater understanding.

*Self-efficacy* was assessed with 9 items from a self-efficacy scale for diabetes self-management [20]. Participants were asked how confident they were that they could perform various self-management tasks (e.g., adjust your insulin correctly when you eat more or less than usual) on 5-point response scales ranging from 1 (not at all confident) to 5 (very confident indeed). Scores on the items were averaged with higher scores indicating stronger self-efficacy.

*Positive and negative outcome expectancies* were assessed with the 24-item outcome expectations scale for diabetes self-management [20]. Participants were asked to rate the extent to which they felt various positive (e.g., keep my diabetes in better control, give me more energy) and negative (e.g., take too much time, make me gain weight) outcomes of diabetes self-management were likely to occur on 5-point response scales ranging from 1 (not at all) to 5 (a lot). Scores on the positive and negative items were averaged with higher scores indicating stronger positive and negative outcome expectancy beliefs, respectively.

Frequency of *self-management behaviours* was assessed using a 10-item measure developed by the research team. Participants were asked to indicate how often they undertook a number of self-management behaviours (e.g., give a correction for snacks) on a 5-point response scale from 1 (never) to 5 (always). Scores on the items were averaged with higher scores indicating greater engagement in self-management behaviours.

*Hypoglycaemic worries* were assessed with the 13-item worries subscale from the Hypoglycaemic Fear Scale [21]. Participants were asked to rate the extent to which they were worried about various negative aspects of hypoglycaemia (e.g., passing out in public) on 5-point response scales ranging from 1 (never) to 5 (always). Scores on the items were averaged with higher scores indicating more worries.

*Cognitive adaptation to diabetes* was assessed with the 7-item, short form of the Child Attitudes to Illness Scale [22]. Participants were asked to rate how often they had a series of feelings about having type 1 diabetes (e.g., that your type 1 diabetes keeps you from doing new things) on 5-point response scales from 1 (never) to 5 (very often). Negative phrased items were reverse-scored and scores on the items were averaged with higher scores indicating a more positive cognitive adaptation to diabetes.

*Diabetes distress* was assessed with the 17-item Diabetes Distress Scale [23]. Participants were asked to rate how distressed they were during the past month by various aspects of diabetes care (e.g., diabetes controls my life) on 5-point response scales ranging from 1 (not a problem for me) to 5 (a serious problem for me). Scores on the items were averaged with higher scores indicating greater diabetes distress.

#### Statistical analyses

Data were entered in SPSS v.23 for analysis. Paired samples t-tests were used to compare HbA1c scores between baseline and six and 12-months for participants from all three centres. Paired samples t-tests were also conducted to compare scores on the self-report measures between baseline and the end of the course for participants from all centres (except for measures of cognitive adaptation to diabetes, diabetes distress and self-management behaviours which were only assessed in the two extended pilot centres), and between baseline and three-month follow-up for participants from the two extended pilot centres. A significance level of 5% was used; no allowance was made for multiplicity of statistical tests.

## Results

#### Participant characteristics

Forty-seven participants were recruited into the study in the pilot centre and completed the self-report measures at the start of the course. Of these participants, 42 (89%) also completed the measures again at the end of the course. In addition, 32 participants were recruited from the two extended pilot centres, of whom 27 (84%) completed the self-report measures at the end of the course and 27 at three-month follow-up. HbA1c scores were obtained for the full sample (N = 79) from all three centres at baseline and for 77 (97%) participants at six-month follow-up and 65 (82%) participants at 12-month follow-up. The characteristics of the baseline sample are reported in Table 1.

#### HbA1c levels

The mean baseline HbA1c score for participants was far above recommended levels (see Table 1). As shown in Table 2, a paired-samples t-test revealed a statistically significant decrease in HbA1c scores from baseline to six-month follow-up in participants who participated in the WICKED course, P = 0.019,  $d_z = 0.273$  (Cohen's d). A similar sized statistically significant reduction in HbA1c scores was also observed between baseline to 12-month follow-up, P = 0.043,  $d_z = 0.257$ . Additional analyses were conducted to examine whether baseline HbA1c scores or reductions in HbA1c scores differed between centres. A one-way ANOVA indicated that that baseline HbA1c scores did not differ statistically significantly between centres (P = 0.130). Similarly, ANCOVAs, controlling for baseline HbA1c scores, indicated that changes in HbA1c scores from baseline to six- (P = 0.637) and 12-month follow-up (P = 0.610) did not differ statistically significantly between centres.

## Self-report outcomes between baseline and the end of the course

A summary of the results comparing scores on the self-report measures between baseline and the end of the course is presented in Table 3. Paired-samples t-tests revealed statistically significant increases in self-report knowledge, P < 0.001,  $d_z = 1.440$ , self-efficacy, P < 0.001,  $d_z = 0.553$ , and positive outcome expectancies, P = 0.038,  $d_z = 0.255$ , and a statistically significant decrease in negative outcome expectancies, P = 0.024,  $d_z = 0.278$ , across all three centres. In contrast, the change in hypoglycaemic worries, P = 0.107,  $d_z = 0.194$ , was non-significant. In addition, a statistically significant increase was observed in self-management behaviours, P = 0.005,  $d_z = 0.228$ ,  $d_z = 0.225$ , and diabetes distress, P = 0.902,  $d_z = 0.023$ , were non-significant.

#### Self-report outcomes between baseline and three-month follow-up

A summary of the results comparing scores on the self-report measures between baseline and three-month follow-up for participants from the extended pilot centres is presented in Table 4. Paired-samples t-tests revealed significant changes in self-report knowledge, P < 0.001,  $d_z = 1.325$ , self-efficacy, P = 0.005,  $d_z = 0.589$ , cognitive adaptation to diabetes, P < 0.001,  $d_z = 1.044$ , and self-management behaviours, P = 0.029,  $d_z = 0.455$ . Changes in positive outcome expectancies, P = 0.214,  $d_z = 0.245$ , negative outcome expectancies, P = 0.443,  $d_z = 0.150$ , hypoglycaemic worries, P = 0.372,  $d_z = 0.175$ , and diabetes distress, P = 0.134,  $d_z = 0.298$ , were non-significant.

### Discussion

The aim of the study was to evaluate a self-management course for young people developed to address their age-specific needs and challenges as a means for helping them improve control of their diabetes. Baseline HbA1c was far from target and well above national guidelines in participants from the three centres but, encouragingly, the results indicated small but statistically significant and clinically meaningful reductions in HbA1c levels from baseline to six and 12-month follow-up. Participants also reported greater knowledge, self-efficacy, and engagement in self-management behaviours and more positive cognitive adaptation to diabetes at three-month follow-up.

While the fall in HbA1c is arguably of primary importance, especially in an age group where many struggle to achieve HbA1c targets, it is equally important to improve knowledge about, confidence in, and performance of, self-management behaviours at a time of transition and increased responsibility and autonomy. The significant increase in cognitive adaptation to diabetes at a time when diabetes can make a young person feel different from peers is also encouraging. It could be that the course helps participants to cognitively adapt to their diabetes by

normalising the experience of diabetes or by providing them the opportunity to reflect on their diabetes thereby aiding greater acceptance. The changes in these psychosocial variables may help young people to improve the management of their diabetes as they enter early adulthood. Accordingly, there is evidence linking self-efficacy and cognitive adaptation to better glycaemic control [24]. The finding that there were no significant increases in hypoglycaemia worries or diabetes distress is also encouraging as it suggests that the course was able to provide information about complications and titrating insulin levels without increasing distress.

The current study has important limitations. In particular, the pre-post (i.e., uncontrolled) design of the study limits the strength of the conclusions. Further research using stronger experimental designs (e.g., RCTs) with larger samples will be required to confirm the current findings. A detailed health economic analysis would also be required to ascertain whether the observed reductions in HbA1c are cost-effective to deliver. There was some attrition in the assessment of the self-report measures at the end of the course in the initial pilot centre (11%) and at three-month follow-up in the extended pilot centres (16%), which will have reduced the statistical power of these analyses. Similarly, it was only possible to obtain HbA1c results for 82% of participants at 12-month follow-up. Finally, the intervention was tested in the same centre that it was developed which could question the generalizability of the study effects. As a result, two additional centres were recruited to provide an extended pilot of the course. This indicates that the course can be delivered effectively in other centres and it is also encouraging that the effects of participation in the course were not moderated by centre.

Notwithstanding these limitations, the current results suggest that a structured education course on self-management may benefit young people with type 1 diabetes. Diabetes education should reflect the developmental needs of young people as neither paediatric courses nor adult courses will match these needs sufficiently. WICKED provides young people with the skills to manage their diabetes at a time of great change and new experiences (such as sex, travel, work, drinking alcohol). As they get older, they may still attend a DAFNE or equivalent course when their priorities change or for a recap on self-management skills such as carbohydrate counting. Our findings support current NICE guidance that self-management education should remain an on-going part of diabetes care. However, given the high Hb1Ac levels found in the current and other studies in the UK [HQIP], structured education programmes alone are unlikely to help young people reach and maintain national and international glucose targets [19, 25].

### Conclusion

Participants reported greater knowledge, greater self-efficacy, and greater engagement in selfmanagement behaviours between baseline and follow up. Encouragingly, statistically significant reductions were observed in HbA1c levels at six- and 12-month follow-up. Further studies should test the efficacy and cost-effectiveness of structured education in a randomised controlled trial. An educational course alone may not achieve maximum benefits for young people, and it is necessary to explore if additional support from the educators delivering the course, parents or clinical teams could be integrated into the care pathway to augment the learning received. One possibility could be reinforcement of key learning from the course over a longer period, by clinical teams and/or parents, to provide greater tailoring of the educational advice to young people's specific challenges and support needs.

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27				
28.		n	%	
29				
30. G	ender			
31.	Male	37	46.8	
32.	Female	42	53.2	
33. Et	hnicity			
34.	White British	74	93.7	
35.	Black British	3	3.9	
36.	British Asian	2	2.6	
37. Di	abetes centre			
38.	Sheffield	47	59.5	
39.	Harrogate	17	21.5	
40.	Leeds	15	19.0	
41.				
42. Pu	ump users	24	30.4	
43				
44.		Mean	SD	
45				
46. Ag	ge (years)	18.55	1.93	
47. BI	VI (kg/m²)	24.16	4.46	
48. Time since diagnosis (years)		7.82	5.65	
49. HbA1c (mmol/mol)		87.78	26.11	
50. HbA1c (%)		10.18	2.39	
51				
52.				

26. **Table 1** Characteristics of the full baseline sample (N = 79)

53.

55						
 56. 57	n	Baseline	Six months	t	Р	dz
58. HbA1c						
59. IFCC units (mmol/mol)	77	88.17 (26.21)	82.73 (24.56)	2.40	0.019	0.273
0. NGSP units (%)		10.21 (2.40)	9.73 (2.24)			
1						
i2. i3	n	Baseline	12 months	t	Ρ	dz
4. HbA1c						
5. IFCC units (mmol/mol)	65	87.80 (24.43)	81.82 (26.14)	2.07	0.043	0.257
6. NGSP units (%)		10.18 (2.23)	9.64 (2.39)			
57						

54. **Table 2** Summary of primary completer analyses for all centres between baseline and six- and 12-month follow-up 55.

68. Note. Means (SDs) are reported.

69.

72. 73	n	Baseline	End of course	t	Р	dz
74. Knowledge	42	3.27 (0.77)	4.41 (0.46)	9.63	<0.001	1.487
75. Self-efficacy	40	3.44 (0.75)	3.83 (0.82)	2.98	0.005	0.471
76. Positive outcome expectancies	39	3.44 (0.83)	3.81 (0.76)	2.24	0.031	0.356
77. Negative outcome expectancies	39	2.48 (1.00)	2.14 (0.87)	1.73	0.092	0.305
78. Hypoglycaemic worries	41	2.23 (0.96)	2.35 (0.85)	1.07	0.291	0.167
79						

70. **Table 3** Summary of secondary completer analyses for the pilot centre 71.

80. Note. Means (SDs) are reported.

81.

82.

84							
 85.	n	Baseline	End of course	3 months	F	Ρ	ρη²
36							
37. Knowledge	24	3.35a (0.75)	4.16b (0.54)	4.17b (0.56)	27.78	<0.001	0.674
8. Self-efficacy	25	2.99a (0.76)	3.42b (0.64)	3.32b (0.69)	6.35	0.006	0.356
9. Positive outcome expectancies	24	3.55 (0.54)	3.55 (0.61)	3.66 (0.52)	0.38	0.687	0.034
0. Negative outcome expectancies	25	2.77 (0.71)	2.60 (0.73)	2.66 (0.64)	1.52	0.239	0.117
1. Hypoglycaemic worries	25	2.20 (0.64)	2.33 (0.65)	2.26 (0.55)	1.20	0.319	0.095
2. Self-management behaviours	24	3.88a (0.62)	4.12b (0.47)	4.05b (0.43)	3.50	0.048	0.241
3. Cognitive adaptation to diabetes	25	2.94a (0.81)	2.98a (0.74)	3.62b (0.44)	17.99	<0.001	0.610
4. Diabetes distress	25	2.21 (0.92)	2.20 (0.87)	1.99 (0.73)	1.42	0.262	0.110
5							

83. **Table 4** Summary of secondary completer analyses for the extended pilot centres

96. *Note*. Means (SDs) are reported. Means with different subscripts differ significantly at P < 0.05.

# Figure 1 WICKED timetable

Monday	Tuesday	Wednesday	Thursday	Friday <i>Go for it</i>	
In the know	HIs and LOs	Back on Track	The road to success		
Know your environment	Results like a pancreas	Results like a pancreas	Results like a pancreas	Results like a pancreas	
Introduction	Break time				
Break time	Corrections and snacks	Break time	Break time	Break time	
Think like a pancreas	Break time	Sick day rules: short- term health	Alcohol and drugs	Eating out	
Break time	Нуроз	Break time	Break time	Break time	
Act like a pancreas	t like a pancreas		Annual review – long Social issues term health		
Lunch - Carbs and Cals	Lunch - Weighing food	Lunch – Using the internet to help with carbohydrate counting	Lunch with guest	Travel to Bowling	
				Bowling	
Results like a pancreas	Exercise	Results like a pancreas	Break time – fresh air	-	
		Take home message	Living with diabetes	1	
Break time	Break time	Early finish	Optional session	Meal out	
Review of the day 1-2-1 time	Results like a pancreas		Results like a pancreas		