

Implementation fidelity of a voluntary sector-led diabetes education programme

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ABSTRACT

Purpose: The quality of voluntary sector-led community health programmes is an important concern for service users, providers and commissioners. Research on the fidelity of programme implementation offers a basis for assessing and further enhancing practice. This paper reports on the fidelity assessment of Living Well, Taking Control (LWTC) – a voluntary sector-led, community-based education programme in England focusing on the prevention and management of type 2 diabetes.

Design/methodology/approach: This fidelity of implementation study was conducted with the Devon-based LWTC programme. A fidelity checklist was developed to analyse audio records of group-based lifestyle education sessions – implementation was rated in terms of adherence to protocol and competence in delivery; the influence of wider contextual factors was also assessed. Kappa statistics (κ) were used to test for inter-rater agreement. Course satisfaction data were used as a supplementary indicator of facilitator competence.

Findings: Analysis of 28 sessions, from five diabetes prevention and two diabetes management groups (total participants, $n=49$), yielded an overall implementation fidelity score of 77.3% for adherence (moderate inter-rater agreement, $\kappa=0.60$) and 95.1% for competence (good inter-rater agreement, $\kappa=0.71$). The diabetes prevention groups consistently achieved higher adherence scores than the diabetes management groups. Facilitator competence was supported by high participant satisfaction ratings.

Originality/value: An appropriate level of implementation fidelity was delivered for the LWTC group-based education programme, which provides some confidence that outcomes from the programme reflected intervention effectiveness. This study demonstrates the viability of assessing the fidelity of implementation in a voluntary sector-led public health initiative and the potential of this method for assuring quality and informing service development.

KEYWORDS

Implementation fidelity; adherence; competence; diabetes education; voluntary sector

PAPER TYPE

Research paper

BACKGROUND

Voluntary sector agencies play an increasingly important role in the delivery of community-based health promotion and disease management programmes. Such agencies may be well placed to engage socially-disadvantaged groups, respond to local health needs, and create innovative and value-for-money interventions (Curry *et al.*, 2011; South, 2015). However, the quality of these initiatives is a key concern for potential service users, commissioners, partner agencies, and other stakeholders. This is partly because voluntary sector agencies are not necessarily subject to the same procedures for quality assurance or the employment of registered professionals as mainstream health service organisations (Baggott, 2013). In this context, research focusing on the fidelity of programme implementation offers a basis for assessing and further enhancing voluntary sector-led practice. The present study reports on one such assessment of Living Well, Taking Control (LWTC) – a voluntary sector-led, community-based type 2 diabetes education programme that focuses on the prevention and management of the condition.

Fidelity of implementation (Foi) refers to the degree to which an intervention is delivered as intended, and is critical to successful translation of evidence-based interventions into practice. Literature reviews have demonstrated that higher fidelity of implementation is associated with greater intervention effects (Durlak and DuPre, 2008; McIntyre *et al.*, 2007). Attaining and demonstrating fidelity enables researchers to identify the active ingredients of an intervention, contrast it with a control or standard treatment, and replicate findings (Hildebrand *et al.*, 2012). Failure to demonstrate fidelity can undermine the internal and external validity of evaluation studies, and makes development of new interventions difficult (Bellg *et al.*, 2004).

Foi is recognised as an important issue for type 2 diabetes prevention programmes. Dunkley *et al.*'s (2014) meta-analysis of pragmatic lifestyle interventions found evidence suggesting that diabetes prevention programmes are effective, but that effectiveness varied substantially between programmes. They concluded that “adherence to international guidelines on intervention content and delivery explained much of the variance in effectiveness” (Dunkley *et al.*, 2014, p. 931). Therefore, the challenge in ensuring effectiveness of such programmes is two-fold – not only does their design need to maximise adherence to guidelines, but also their implementation needs to adhere to that specified design – there needs to be evidence of implementation fidelity.

There are several barriers to maintaining Foi in community settings, which include adaptations of interventions to the local context, limited pre-implementation specification and training, individual variations in facilitator adherence and competence, lack of technical support and ongoing monitoring, limited resources for supporting the intervention at the site level, the learning effect of facilitators in line with programme development over time, and competing demands for the facilitators' time that can diminish their commitment or effectiveness (Cross and West, 2011; Breitenstein *et al.*, 2010; Andersen *et al.*, 2014). It is essential to outline clear and feasible strategies for monitoring, measuring, and ensuring Foi to avoid potentially useful interventions appearing to be ineffective (Breitenstein *et al.*, 2010). Furthermore, non-systematic assessments of Foi can decrease the quality and usefulness of fidelity data (Nelson *et al.*, 2012).

According to Borrelli (2011), there are five domains of fidelity: study design, training, intervention delivery, intervention receipt, and intervention enactment (defined as the extent to which participants apply the skills learnt). The heart of fidelity is often considered to be intervention delivery, the core components of which are adherence and competence (Mars *et al.*, 2013; Gearing *et al.*, 2011). Whilst adherence is concerned with *the extent* to which the intervention protocol is implemented, competence refers to *how well* the protocol is implemented and delivered (Breitenstein *et al.*, 2010). Adherence measures, therefore, evaluate the presence or absence of components that are considered to be specific, essential and optional to the defined intervention. If facilitators are found to be drifting

from the protocol, then remedies such as feedback, individualised coaching, and group discussion may be applied to identify and remove obstacles to fidelity (Whitmer *et al.*, 2005). Competence measures include facilitator qualities related to communication, technical abilities, and skills in responding to the needs of intervention participants (Breitenstein *et al.*, 2010). Due in part to the methodological difficulties surrounding the monitoring and measurement of competence, this aspect is less often assessed and reported in literature than adherence (Cross and West, 2011; Mars *et al.*, 2013).

In addition to adherence and competence, Fof studies of intervention delivery need to take into account the programme context (Breitenstein *et al.*, 2010). Contextual factors such as group dynamics, unplanned interruptions, or the point of assessment in the programme's delivery, can influence the ability of facilitators to deliver an intervention (Durlak and DuPre, 2008; Fixsen *et al.*, 2005). Assessment of the role of contextual factors is key to gaining a broader understanding of the programme's implementation and of environmental settings that can enhance or impede delivery, which subsequently impacts the interpretation and generalisation of the evaluation outcomes (Moore *et al.*, 2015).

This study aimed to assess the fidelity of implementation of the LWTC programme, with a focus on intervention delivery in terms of both adherence and competence.

METHODS

Study setting: Living Well, Taking Control programme structure and delivery

Living Well, Taking Control (LWTC) is a lifestyle behaviour change programme developed by two UK voluntary sector agencies – Westbank Community Health and Care, Devon, and Health Exchange, Birmingham. LWTC focuses on the prevention and management of type 2 diabetes, in non-clinical, community settings. In 2013, funding obtained as part of the Big Lottery Fund's Wellbeing initiative provided developers with the opportunity to roll out the LWTC programme across four sites in the UK (Devon, Birmingham, Newcastle, and Darlington), and align its delivery to national best practice guidance (NICE, 2016; NICE, 2015; NICE, 2012; DoH, 2012; DoH, 2001). The present Fof study focused on the Devon-based delivery of the programme by Westbank.

The core component of the LWTC programme is a group-based, structured lifestyle education intervention to promote sustainable healthy lifestyle changes for people with Impaired Glucose Regulation (IGR, also known as pre-diabetes or non-diabetic hyperglycaemia) and those newly diagnosed with type 2 diabetes (T2D). Participants are allowed to have a carer, partner, or other family member attend the education sessions with them to provide support. The intervention is based around the use of behaviour change processes and techniques derived from self-regulation theories, such as the Social Cognitive Theory (Bandura, 1985) and Control Theory (Carver and Scheier, 1982). These include goal-setting, action-planning, self-monitoring, progress feedback, problem-solving, and reviewing goals. Group-based interventions have been shown to be effective for diabetes prevention, self-management and support, providing an environment that facilitates peer discussions about problems and personal experiences, resulting in significant benefits, including weight loss, improved fasting glucose levels, improved energy, and improved emotional state (Katula *et al.*, 2011; Trento *et al.*, 2010; Holma *et al.*, 2008).

Programme structure and delivery

In order to standardise the intervention structure, content and delivery, LWTC programme partners developed protocol manuals for the diabetes prevention and management education sessions, to train and guide programme facilitators to provide comprehensive lifestyle advice. The facilitators were also provided two days of training in the use of a person-centred, empathy-building approach to

delivering the intervention, based on the use of motivational interviewing techniques to explore and enhance motivation, exchange information, and deliver other elements of the programme, such as reviewing progress and problem-solving (Miller and Rollnick, 2002). Programme facilitators were recruited from backgrounds that included undergraduate education in health promotion, physical activity and nutrition. All facilitators had been employed since the inception of the programme, 15 months prior to the present study being undertaken.

As per NICE recommendations, the programme aims to give participants at least 16 hours of contact time, through a combination of group and one-to-one sessions. At the start of the programme, participants receive a one-hour individual introduction session where they meet the facilitator, have the opportunity to ask questions, and complete baseline measures (see below). Participants then attend four group-based education sessions over four weeks, each covering a different component: pre-diabetes/T2D and a healthy lifestyle, healthy eating, physical activity, and positive mental health and wellbeing. The first session is scheduled for an hour, and subsequent sessions are two hours each.

At the end of the four-week group sessions, participants are offered one-to-one or group follow-up contacts at 2, 3, 6, 9, and 12 months to review goals, reflect on changes made, and identify the need for any additional contacts focusing in more detail on certain aspects of the programme (e.g., nutrition, physical activity, wellbeing) or support through local community services (e.g., smoking cessation, alcohol reduction, health trainer). Biometric measures – weight, height, body mass index (BMI), and blood pressure (BP) – are obtained at baseline, on week 4 of the group sessions, and during follow-up contacts at 2, 3, 6, 9 and 12 months. Glycated haemoglobin (HbA1C) levels are assessed at baseline, 6 months and 12 months.

Data collection

Data for the FoI study was collected primarily through audio recordings of programme group sessions delivered by each of the two facilitators at Westbank. In order to prevent selection bias and ensure an adequate-sized and representative sample, all sessions delivered from 20th January to 5th March 2015 were audio-recorded. There were five diabetes prevention and two diabetes management groups during this period. Verbal and written consent were sought from participants and any accompanying persons (i.e. partners or family members) at the start of the first session. None of the participants declined to provide consent for recording, giving a total of 49 hours of recording from 28 group sessions. Audio-recorded data was supplemented by a feedback questionnaire, which participants completed at the end of the four-week group sessions to rate their satisfaction with the programme and the facilitators.

Data coding and analysis

In line with the Medical Research Council's (MRC) recommendations for process evaluation (Moore *et al.*, 2015), the FoI analysis and initial reporting were conducted prior to knowledge of outcomes effects to guard against interpretation bias. Information from the questionnaire that participants completed as part of the wider service evaluation was used to conduct T-tests to assess if there were any significant differences between the participant characteristics of the FoI study sample compared to the overall Westbank population of programme participants – the FoI study sample is a subset of the overall Westbank population.

Audio recordings were assessed by a principal rater (MK) and reviewed by a second member of the research team (RA or ON), using a fidelity checklist. The fidelity criteria were developed to reflect key elements of the standardised programme protocols, with input from the facilitators and managers. The initial checklist was piloted with recordings from the first group that underwent each of the programme sessions, after which minor revisions were made.

The final checklist comprised a total of 62 compulsory and 14 optional items. The overall structure of the checklist is shown in Table 1 and full details are in Supplementary File 1.

Table 1 Structure of the LWTC fidelity checklist

Session: Programme component	No. of compulsory items	No. of optional items
1: Pre-diabetes/T2D and a healthy lifestyle	Adherence items : 11 Competence items : 5 Total : 16	2
2: Healthy eating	Adherence items : 13 Competence items : 3 Total : 16	1
3: Physical activity	Adherence items : 11 Competence items : 3 Total : 14	6 (3 of these applied to diabetes patients only)
4: Positive mental health and wellbeing	Adherence items : 13 Competence items : 3 Total : 16	5

The two core components of intervention delivery were defined as follows:

- Adherence – the extent to which facilitators followed the programme protocols, e.g., providing essential information, presenting benefits of and barriers to change, and undertaking goal setting activities.
- Competence – the facilitators’ skills in delivering the programme, including communication skills, e.g., through creating opportunities for participants to ask questions or lead group discussions, and reminding participants of earlier commitments.

The FoI for each item was rated as ‘low/not observed’ (scored 1), ‘observed to a small degree’ (scored 2), ‘observed to a medium degree’ (scored 3), or ‘high implementation’ (scored 4). FoI scores for adherence and competence were obtained as mean scores across the compulsory items. An overall FoI score for each group was the mean score from across the four sessions converted into a percentage. Although there is no agreement from existing literature as to what constitutes an acceptable level of implementation fidelity (Breitenstein *et al.*, 2010), the goal for this assessment was set at a minimum of 80%.

In addition to adherence and competence ratings, any notable observations on group dynamics and contextual variations from the audio recordings were documented separately on, for example, verbal comments about the group made by the facilitator, interruptions and deviations. Supplemented by data from the course satisfaction feedback forms, a list of factors that appeared to either enhance or impede programme delivery was developed through open coding and iterative clustering of the observational notes, to provide a broad understanding of facilitators’ competence.

Reliability and validity

To ensure reliability and internal consistency, ten percent of the audio-recorded intervention sessions were tested for inter-rater agreement (Mars *et al.*, 2013). Two independent raters (RA and ON) were specifically recruited to analyse five hours of recordings each. An online random sequence generator was utilised to randomly select groups and sessions for analysis. Kappa statistics (κ) were calculated using SPSS Statistics for Windows, Version 22.0 (Armonk, NY: IBM Corp.), as an index of inter-rater agreement for compulsory adherence and competence items, and interpreted using benchmarks

published by Peat (Peat, 2001), with <0.4 indicating poor agreement; 0.41–0.60 fair; 0.61–0.80 good; and 0.81–1.00 very good agreement. P-values were also calculated to test whether the estimated kappa was not due to chance, with significance set at $p < 0.05$ (Viera and Garrett, 2005).

RESULTS

Group and participant characteristics

There were 49 participants across the seven groups that received the intervention during the study period, a median of 7 participants per group (range 3 to 9). Table 2 shows a breakdown of the number of participants per group, and any partners or family members who were consistently present to provide support during sessions.

Table 2 Group sizes and composition in the fidelity assessment

Group ID (P: pre-diabetes; D: diabetes)	No. of participants	No. of partners/family members	Total
P31	8	0	8
P32	7	2	9
P33	7	1	8
P34	9	3	12
P35	8	1	9
'Pre-diabetes' sub-total	39	7	46
D20	7	1	8
D21	3	1	4
'Diabetes' sub-total	10	2	12
Total	49	9	58

Results of T-tests (see Table 3) found no difference between the participants in the groups used for fidelity assessment ($n=46$) compared to the overall Westbank programme participants ($n=322$) in terms of gender, ethnicity, employment status, BMI, waist circumference, general health, life satisfaction, level of physical activity, and smoking and disability status. However:

- Participants in the FoI study were significantly heavier ($p < 0.05$) on entry to the programme, but had a significantly lower HbA1c ($p < 0.05$) than the programme participants overall.
- The programme participants overall had a significantly higher education level than participants in the FoI study ($p < 0.05$).

The study sample was considered to be generally representative of the wider Westbank participant population; differences were not expected to affect fidelity.

Table 3 Comparison of participant characteristics between fidelity groups and the overall Westbank group

Participant characteristics		Fidelity groups (n=46*)	Overall Westbank group (n=322)	p-value
Age range		39-80 years	28-91 years	
Diagnosis	Pre-diabetes	80.4%	68.2%	p=0.49
	Diabetes	19.6%	31.8%	
Gender	Male	43.5%	40.2%	p=0.31
	Female	56.5%	59.8%	
Ethnicity	White	82.2%	87.8%	p=0.16
Body mass index (BMI)	Normal weight	7%	12%	p=0.25
	Overweight	37.2%	37.1%	
	Obese	55.8%	50.8%	
Weight	Mean	91.3kg (SD 18.3)	86.1kg (SD 18.3)	p=0.02
	Range	57.8-130.8kg	56.7-152.2kg	
Waist circumference	Mean	106.8cm (SD 14.1)	103.5cm (SD 15.1)	p=0.07
	Range	82-140cm	69-174.5cm	
HbA1c	Mean	42.4 mmol/mol (SD 4.4)	45.4 mmol/mol (SD 9.0)	p=0.04
	Range	36-53 mmol/mol	32-109 mmol/mol	
Health	Mean	68.1 (SD 23.9)	71.1 (SD 20.8)	p=0.34
	Range	14-100	7-100	
Life satisfaction	Mean	7.1 (SD 2.2)	7.4 (SD 2.0)	p=0.25
	Range	2-10	0-10	
Physical activity	Met guidelines	66.7%	59.8%	p=0.50
Employment	Retired	62.2%	48.7%	p=0.95
	Employed	8.9%	24.8%	
	Self-employed	6.7%	7.9%	
	Unemployed	4.4%	1.9%	
	Carer	0%	2.2%	
	Student	2.2%	0.9%	
	Long-term sickness/disabled	2.2%	3.1%	
Education	Completed school up to 16 years	40.9%	36.9%	p=0.004
	Did some extra training or A levels	34.1%	41.2%	
	Did an undergraduate or postgraduate degree	15.9%	21.9%	
Smoking status	Non-smokers	83.7%	92.5%	p=0.37
Disability	No disability	69.2%	81.3%	p=0.32

*Data was available for 46 out of the 49 participants included in the FoI analysis, either due to refusal to answer the questionnaire or failure to return it. The small amount of missing data is unlikely to have any significant effect on the T-test results.

Adherence to intervention protocol

Data on adherence to the LWTC intervention protocol are shown in Table 4. Inter-rater agreement for adherence criteria was moderate ($\kappa=0.60$, $p<0.001$). The pre-diabetes groups scored higher than the diabetes groups in all sessions.

Table 4 Implementation fidelity scores for adherence criteria

Group ID (P: pre-diabetes; D: diabetes)	Implementation fidelity scores for adherence items, from 1 (low) to 4 (high)				
	Session 1	Session 2	Session 3	Session 4	Overall
P31	3.55	3.31	3.55	2.54	3.21
P32	3.56	2.92	3.36	3.00	3.17
P33	3.73	3.00	3.64	2.62	3.21
P34	3.73	3.08	3.55	2.77	3.25
P35	3.64	3.00	3.73	2.85	3.27
Mean for 'pre-diabetes'	3.64	3.06	3.57	2.76	3.22
D20	3.45	2.62	3.09	2.31	2.83
D21	2.82	2.77	2.82	2.46	2.71
Mean for 'diabetes'	3.14	2.70	2.96	2.39	2.77
Overall mean	3.50	2.96	3.39	2.65	3.09
	87.43%	73.93%	84.79%	66.25%	77.32%

Sessions 1 and 3 overall exceeded the 80% minimum target for acceptable mean implementation fidelity score. Items that were rated as 'high implementation' for all groups are summarised in Table 5, for example, assessing the importance and confidence in making healthy lifestyle changes, introducing the 'Eatwell Plate', and discussing the benefits of physical activity. Session 4, which focused on positive mental health and wellbeing, consistently scored the lowest out of the four sessions for all groups. However, every session had adherence criteria that were often either not mentioned by the facilitators or only very briefly mentioned, for example, recapping and assessing retention from the previous session, discussing the importance and confidence to maintain healthy emotional wellbeing, and setting new goals for future – these are also summarised in Table 5.

Table 5 Summary of adherence criteria that were highly implemented or commonly omitted/implemented at a low level, across all sessions

Highly implemented adherence criteria across all sessions (i.e., scored 4) <i>[Note: There were no adherence criteria highly implemented in Session 4]</i>	
Providing information	<ul style="list-style-type: none"> • Overview of what diabetes/pre-diabetes is • Introduction to the 5 key healthy lifestyle messages • Explaining clinical metrics • Introduction to the 'Eatwell Plate' and food labelling • Introduction to physical activity guidelines
Assessing motivation	<ul style="list-style-type: none"> • Assessing importance and confidence in making healthy lifestyle changes, healthy dietary changes, and/or to increase physical activity
Discussing key elements	<ul style="list-style-type: none"> • Discussing the importance of low fat and high fibre diets, and about each of the food groups • Discussing the benefits of physical activity, and the different types of activity
Adherence criteria commonly omitted/implemented at a low level across all sessions (i.e., scored 1)	
Comprehension and retention of information	<ul style="list-style-type: none"> • Recap and assess retention from previous week's session • Review all items at the end of Session 4
Activity diaries	<ul style="list-style-type: none"> • Remind participants to complete activity diary in time for Session 3 • Monitor awareness and reflection of physical activity undertaken, and assess motivation to increase activity levels

Positive thinking	<ul style="list-style-type: none"> • Introduction to the concept of positive thinking • Importance and confidence to maintain healthy emotional wellbeing • Barriers to positive thinking
Goal setting	<ul style="list-style-type: none"> • Review goals set, and set new goals for future

Competence in intervention delivery

Table 6 shows that the overall implementation fidelity scores for each session ranged from 3.71 (92.8%) to 3.93 (98.3%), which indicates a high level of competence in intervention delivery across all groups. Inter-rater agreement for competence criteria was good ($\kappa=0.71$, $p<0.001$). Facilitators did not achieve full implementation scores for Session 1, most commonly due to omission of the 'confidentiality agreement' criterion, which is a measure of how competent the facilitators were in creating an environment where participants could openly and comfortably express themselves and share opinions, with the assurance that all information would be kept private and confidential (all participants had already provided verbal and written consent at the start of the session).

Table 6 Implementation fidelity scores for competence criteria

Group ID (P: pre-diabetes; D: diabetes)	Implementation fidelity scores for competence items, from 1 (low) to 4 (high)				
	Session 1	Session 2	Session 3	Session 4	Overall
P31	3.40	4.00	4.00	4.00	3.79
P32	3.25	4.00	4.00	4.00	3.77
P33	3.80	4.00	4.00	4.00	3.93
P34	3.60	4.00	4.00	4.00	3.86
P35	3.20	4.00	4.00	4.00	3.71
D20	3.40	4.00	4.00	4.00	3.79
D21	3.40	4.00	4.00	4.00	3.79
Overall mean	3.44 85.89%	4.00 100.00%	4.00 100.00%	4.00 100.00%	3.81 95.14%

Course satisfaction data were available for 31 out of the 49 participants (63.3%). The other participants had either not attended Session 4 and hence did not receive the course satisfaction questionnaire, or they had not returned the questionnaire after completion. Table 7 shows the data alongside that of the wider LWTC programme population at Westbank. Overall, the FoI sub-sample of participants gave high satisfaction ratings for the LWTC programme, which is similar to ratings of the wider group. This not only affirms facilitator competence in intervention delivery, but indicates potential generalisability of the FoI findings across the whole programme.

Table 7 Course satisfaction data

	Fidelity groups	Overall Westbank group
Did the course benefit you? <i>No. (%) of participants who responded 'yes'</i>	30 (96.8%) Total n = 31	232 (98.7%) Total n = 235
On a scale from 1-10, how much did you enjoy the course? [1: Not at all - 10: Very]	Mean = 9.13 Range 7-10 Total n = 31	Mean = 8.84 Range 1-10 Total n = 237
Did the course meet your specific needs?* <i>No. (%) of participants who responded 'yes'</i>	30 (96.8%) Total n = 31	213 (97.7%) Total n = 218

On a scale from 1-10, how much would you recommend this course to friends or family? [1:Extremely unlikely - 10: Extremely likely]	Mean = 9.23 Range 5-10 Total n = 31	Mean = 9.13 Range 2-10 Total n = 184
*One participant did not answer this question because it was “difficult to say due to [my] disability”.		

Implementation of optional items

The overall level of implementation of optional items ranged from 45.5% to 63.6% across all groups. ‘Offering refreshments’ and ‘repeating clinical metrics’ were always implemented. The optional walk or seated exercise in Session 3 was only provided for one group, while the relaxation exercise in Session 4 was never delivered. Mental health concerns were not raised in Session 4, therefore there was no signposting. Other forms of signposting i.e. to healthcare professionals, local services (e.g. smoking cessation, alcohol reduction) or additional support were carried out as required. There were three additional optional items for participants with diabetes: expectations from healthcare professional, information about annual reviews, and the 15 Healthcare Essentials – none of these were implemented for either diabetes group.

Group dynamics and contextual factors

Analysis of the recordings and course satisfaction feedback forms identified no unplanned disruptions or curtailed sessions due to an external interruption. Participants did not report problems with the venues and facilities and there were no instances of disruptive behaviour by individuals.

Group verbal interactions changed over the duration of the course, but not necessarily in a consistent way for all groups – in four groups there was high level verbal interaction from the outset of the course; by contrast, three other groups started off with very few verbal contributions from participants, but participants engaged in dialogue more fully after the end of the first session. Group size also influenced verbal interactions. Participants in the smallest group (D21) had more opportunities to participate in discussion than those in the other groups. One D21 participant expressed that it was “so much easier and more comfortable to ask questions at this session, compared to the other diabetes session [conducted by another organisation]”.

In six out of the seven groups, at least one participant brought a family member, who was usually their partner. Family members asked questions, raised points of clarification and, in most cases, actively contributed to the group discussion items. There was no evidence from the course feedback that participants objected to the presence of the family members of others in the group. The presence of these individuals appeared to facilitate group interactions and personal support. Overall, the frequency, breadth, and content of verbal interactions indicated good group dynamics across the groups. For each session, all participants made at least one verbal contribution, and many offered verbal support to one another in response to personal disclosures.

Data from audio recordings indicate that participant characteristics may have affected group dynamics and delivery, particularly in group D20 where during the sessions, the facilitator described the group as “well-informed” and “well-read”, and expressed that “time always ran away” with this group. Analysis of the delivery of session items to this group recorded facilitator communication that was diverted by the direction of participant-led conversations. Although implementation ratings for adherence items imply that these factors impeded delivery in group D20, it may also have demonstrated the ability of the facilitator to adapt in response to the specific needs of the group. Two groups had participants who expressed sceptical views and were less receptive to the idea of behaviour change than others in the group. Some concerns were expressed by participants with diabetes about symptoms, medications, and other topics that were not covered within the scope of the programme.

DISCUSSION

This study has designed a fidelity assessment tool and successfully applied it to a voluntary sector-led public health initiative to provide insights into its implementation. The FoI for the overall LWTC programme was satisfactory in terms of adherence to the protocol, with a high level of competence in delivery. The p-values obtained for inter-rater agreement for both adherence and competence criteria, show that the level of agreement was not due to chance ($p < 0.001$). The moderate inter-rater agreement for the adherence criteria may have been influenced by the raters having varying interpretations of some of the criteria, and applying different levels of rigour. Overall, it appears that fidelity assessment tools, such as the type developed in the present study, can have a role in assessing and assuring the quality of initiatives delivered through voluntary sector agencies.

There were variations across the groups – the mean implementation fidelity score for adherence criteria for the pre-diabetes groups, was 80.6%, which is considered an acceptable level of adherence according to precedents set by other studies (Breitenstein *et al.*, 2010). However, the mean adherence score for the diabetes groups was 69.3% - participants in these two groups came across as more knowledgeable, opinionated, inquisitive, and were more actively engaged in discussions. Given the nature of the diabetes groups, it would have been challenging for the facilitator to address as many of the participants' questions within the time allocated for each session, while still adhering to the protocol. This reflects some of the pedagogical challenges faced by educators in other diabetes group-based programmes (Andersen *et al.*, 2014). Nevertheless, intentional and/or unintentional adaptations of interventions, including changes to programme delivery and not completing core elements, are common and natural in community-based settings for reasons such as to generate/maintain participant engagement or to cope with barriers like time constraints (Carvalho *et al.*, 2013). The balance between fidelity and adaptation needs to be continuously monitored and evaluated, to ensure that the intervention remains relevant to participants' needs and still leads to the desired outcomes (*ibid*).

The optional walk or seated exercise was only offered to one pre-diabetes group, and carried out by the facilitator whose expertise was in physical activity. Lack of suitable equipment on location, lack of facilitator expertise, or insufficient time, are several possible reasons why the optional activities or items were not implemented more often. The consent process for recording of the sessions took place for all groups at the start of Session 1. Since the recorder might not have been switched on by then, the 'confidentiality agreement' criterion was not captured in four out of the seven groups, and was therefore scored as 'not observed'. This highlights that effective data capture through audio recording is dependent on facilitators remembering to switch on the recorder at the right time.

There were also variations across the sessions, with omissions occurring most notably in Sessions 3 and 4. Physical activity diaries were not reviewed during Session 3 – in four out of the seven groups, there was no mention of it by the facilitator; participants in the other three groups did not use the diaries, and therefore they could not be discussed. This may be expected since in the prior session, facilitators did not remind participants to complete the activity diary. Nevertheless, the facilitators still assessed whether the participants managed to make any changes in their level of activity since the last session, or had any motivation or plans to increase it.

The facilitators had not received training in the area of mental health and wellbeing, which might have affected their confidence in delivering this particular component in Session 4. Since evidence suggests that mental health and wellbeing are crucial factors in enabling participants to make positive and lasting lifestyle changes (NHS Confederation, 2011), it would be interesting to see how its omission/low level of implementation would affect intervention effectiveness. Goal-setting and reviewing goals play important roles in the programme to translate motivations into action, and to

support longer-term maintenance of behaviour change (Bandura, 1985; Carver and Scheier, 1982). While goal-setting was well implemented in the first three sessions, especially for the pre-diabetes groups, reviewing of goals and setting new goals were mostly omitted or implemented at a low level in Session 4. It is possible that this might have been due to time constraints toward the end of the session.

The supplementary qualitative analysis was useful to provide a general insight into group dynamics and contextual factors. The FoI study sample was largely similar to the wider LWTC programme participant population and reflected a typical context for delivery. However, there were a number of limitations to the present study. Audio recordings could not capture non-verbal aspects and environmental factors (e.g., cramped intervention venue, extraneous events that distract participants), therefore, it could not be determined if these issues occurred or how they might have influenced facilitators' adherence and competence. Although results show a high overall level of implementation and competence, the accuracy of these ratings might have been undermined by the method of assessment used.

The FoI findings point towards several areas for improvement. The programme protocol needs to give clearer guidance and enhance facilitator training in the area of mental health and wellbeing, in order to improve delivery of that intervention component. This form of guidance is likely to be particularly important where initiatives, such as those often found in the voluntary sector, are delivered by facilitators with less advanced professional healthcare training. Further research is needed to establish fidelity measures with optimal validity and reliability. A six-point Likert scale that incorporates the Dreyfus system (Dreyfus, 1989) for denoting competence may be a more robust method of assessing both adherence to intervention protocol and skill of the facilitator in intervention delivery. Such scaling could have a role in setting higher assessment point thresholds, which in turn, can help drive up standards of implementation when used over time. Interviews and focus groups would provide more robust and in-depth qualitative data for a more comprehensive understanding of the intervention delivery. It would also be useful for future research to further assess the impact that group size, group dynamics and age differences between participants within a group have on the FoI of group-based interventions.

CONCLUSION

In conclusion, the study suggests that an appropriate level of implementation fidelity was generally achieved for the LWTC group-based education intervention with a satisfactory level of adherence to the protocol and a high level of competence in delivery. The development of standardised protocol manuals for intervention design and training were critical to ensuring fidelity of implementation. However, a higher level of implementation fidelity would have been more desirable to increase confidence in the interpretation of findings around intervention outcomes and effectiveness. The eventual outcomes of the associated evaluation studies will help to determine if components that were omitted or implemented at a low level were crucial to ensuring effectiveness of the intervention, and whether adjustments are needed to the intervention and training protocols. This study has shown that it is feasible and valuable to evaluate the fidelity of implementation of a voluntary sector-led public health initiative for quality assurance and practice enhancement.

LIST OF ABBREVIATIONS

BMI: Body Mass Index; **FoI:** Fidelity of implementation; **HbA1c:** Glycated haemoglobin; **LWTC:** Living Well, Taking Control; **NICE:** National Institute for Health and Care Excellence; **T2D:** Type 2 diabetes

COMPLIANCE WITH ETHICAL STANDARDS

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

This study was given ethics approval by the University of the West of England's 'University Ethics Committee' (Ref: HAS/14/03/49). All potential participants were provided with written and verbal information about the study, opportunities for withdrawal of data, and asked to complete a consent form.

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CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

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SUPPLEMENTARY FILE 1

LWTC Audio Recording Fidelity Checklist

Session 1: Diabetes/Pre-diabetes and a healthy lifestyle	Level of implementation				Notes
	Low/Not observed	Observed to a small degree	Observed to a medium degree	High implementation	
Friendly welcome					
Refreshments offered (tea, coffee, water) ***OPTIONAL – Depends on location***					
Introductions					
Confidentiality agreement (e.g., what is said in the room, stays in the room etc.,)					
Course aims and objectives (brief run-through of what the programme will entail)					
Opportunity for participants to ask questions					
Participants asked about what they expect from the programme (e.g., hopes and fears)					
Assess importance and confidence in making healthy lifestyle changes					
Assess understanding of the condition (knowledge prior to the course beginning)					
Overview of what diabetes/pre-diabetes is					
Overview of complications associated with diabetes					

Introduce 5 key healthy lifestyle messages (1. Eating a healthy diet, 2. Undertaking regular activity, 3. Achieving and maintaining a healthy weight, 4. Positive mental health and wellbeing, 5. Making healthy lifestyle choices)					
Explore benefits and challenges to change (understand journey and available support, understand and address potential barriers, reference to the stages of change model)					
Clinical metrics explained (understand what readings mean, what normal/high levels are, and reasons for reviewing them)					
Signpost to Health Care Professional (e.g., how to access local HCP) ***OPTIONAL – Only if participant mentions issue***					
Goal setting (ensure participants are aware of what they would like to achieve from attending the course, and encourage behaviour change, reference to SMART goals, use goal setting tool)					
Food and activity diaries (introduce/remind participants to complete food and activity diaries for the following weeks' sessions)					
Opportunity and encouragement for participant-led group discussion					

Note: Items not highlighted are 'adherence' criteria; items highlighted green are 'competence' criteria; items highlighted grey are optional.

Session 2: Healthy eating	Level of implementation				Notes
	Low/Not observed	Observed to a small degree	Observed to a medium degree	High implementation	
Friendly welcome					
Refreshments offered (tea, coffee, water) ***OPTIONAL – Depends on location***					
Recap previous week’s session ('Diabetes/pre-diabetes and a healthy lifestyle')					
Opportunity for participants to ask questions					
Assess retention from Session 1 (assess group and individual understanding, signpost for further support if required)					
Assess group and individual understanding of healthy eating					
Assess importance and confidence to make healthy dietary changes (encourage group interaction, motivation, and behaviour change)					
Discuss the importance of low fat and high fibre diets for diabetes prevention/management					
Introduction to the 'Eatwell Plate'					
Discussion about each of the food groups (fat, carbohydrates, dairy, protein, fruit, vegetables, drinks and alcohol)					
Barriers to healthy eating (discussion around the group’s perceived barriers to healthy eating and possible solutions)					

Food labelling (awareness of food labelling and terms to watch out for on packaging, use example packaging as reference)					
Food diaries – dietary assessment (individual and group understanding of current diet, and identification of ways in which to improve)					
Positive thinking (introduce the group to the concept of positive thinking)					
Goal setting (understanding of how goals can be achieved, encourage behaviour change, use goal setting tool)					
Activity diary (remind participants to complete activity diary in time for Session 3)					
Opportunity and encouragement for participant-led group discussion					

Note: Items not highlighted are 'adherence' criteria; items highlighted green are 'competence' criteria; items highlighted grey are optional.

Session 3: Physical activity	Level of implementation				Notes
	Low/Not observed	Observed to a small degree	Observed to a medium degree	High implementation	
Friendly welcome					
Refreshments offered (tea, coffee, water) ***OPTIONAL – Depends on location***					
Recap previous week’s session ('Healthy eating')					
Review food diaries / progress (allow participants to raise concern over food eaten and guide them in making positive changes to their diet)					
Opportunity for participants to ask questions					
Assess retention from Session 2 (assess group and individual understanding, signpost for further support if required)					
Assess importance and confidence to increase physical activity (encourage group interaction, motivation, and behaviour change)					
Discuss what physical activity is (with examples and reassurance)					
Introduce the physical activity guidelines (assess group understanding)					
Discuss and review activity levels (encourage participants to achieve recommended levels of physical activity)					
Discuss the benefits of physical activity, and the different types of activity					

Discuss the barriers to physical activity (and how to overcome them)					
Signpost participants to further support if required (e.g., local access, GP referral, additional support) **OPTIONAL**					
Activity diary (monitor awareness and reflection of physical activity undertaken, assess motivation to increase activity levels)					
Goal setting (understanding of how goals can be achieved, encourage behaviour change, use goal setting tool)					
Optional activity: walk or seated exercise (promote easy accessible form of physical activity)					
Opportunity and encouragement for participant-led group discussion					
Diabetes patients only Expectations from your health care professional (what to expect from your GP, practice nurse etc)					
Diabetes patients only Annual Reviews (e.g., what is included? How often? What will happen?)					
Diabetes patients only 15 Healthcare Essentials					

Note: Items not highlighted are 'adherence' criteria; items highlighted green are 'competence' criteria; items highlighted grey are optional.

Session 4: Positive mental health & wellbeing	Level of implementation				Notes
	Low/Not observed	Observed to a small degree	Observed to a medium degree	High implementation	
Friendly welcome					
Refreshments offered (tea, coffee, water) ***OPTIONAL – Depends on location***					
Recap previous week’s session ('Physical activity')					
Review activity diaries / progress (allow participants to raise concern over physical activity undertaken and guide them in making positive changes to their activity levels)					
Opportunity for participants to ask questions					
Assess retention from Session 3 (assess group and individual understanding, signpost for further support if required)					
Assess importance and confidence to maintain healthy emotional wellbeing (encourage group interaction, motivation, and behaviour change)					
Positive thinking (promote positive mental health and well-being)					
Signpost if any mental health concerns are raised ***OPTIONAL***					
Understand current feelings and thoughts about positive thinking					
Discuss barriers to positive thinking					

Relaxation techniques (demonstrate and encourage relaxation techniques to promote greater wellbeing)					
Relaxation exercise ***OPTIONAL***					
Review goals set (monitor goals set at the beginning/during the course, and discuss barriers if these have not been fulfilled)					
Set new goals for future					
Review all topics (ensure participants have relevant information for making positive lifestyle changes)					
Signpost to local services if required (e.g., smoking cessation, health trainer, alcohol reduction) ***OPTIONAL***					
Agree follow-up route (clear understanding of next steps and programme continuation)					
Opportunity and encouragement for participant-led group discussion					
Complete end of course questionnaire (course satisfaction data)					
Optional Repeat clinical metrics					

Note: Items not highlighted are 'adherence' criteria; items highlighted green are 'competence' criteria; items highlighted grey are optional.