Living Well, Taking Control
Fidelity of Implementation Study

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June 2015

ACKNOWLEDGEMENTS

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ISBN: 9781860435324

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EXECUTIVE SUMMARY

Background

Living Well, Taking Control (LWTC) is a community-based diabetes prevention and management programme. The core component involves a group-based education intervention that delivers a series of structured sessions to promote sustainable healthy lifestyle changes for people with Impaired Glucose Regulation (also known as 'pre-diabetes' or non-diabetic hyperglycaemia) and those newly diagnosed with type 2 diabetes (T2D). LWTC is a programme developed by two third sector agencies: Health Exchange based in Birmingham and Westbank Community Health Care based in Exminster, Devon.

The current Fidelity of Implementation (FoI) study is part of a wider process evaluation of LWTC to determine the degree to which the intervention is delivered as intended, and is critical to successful translation of evidence-based interventions into practice.

Research Aim

The aim of this study is to assess the fidelity of implementation of the LWTC programme, with a focus on facilitator adherence and competence.

Methods

Fidelity of implementation was primarily assessed using a checklist to analyse audio recordings of all group sessions conducted by Westbank from 20th January to 5th March 2015.

Findings

The overall level of implementation score was 78.2% for adherence to intervention protocol, and 88.7% for competence in intervention delivery. The 'pre-diabetes' groups scored higher than the diabetes groups in all sessions, with regards to adherence. Facilitator competence was supported by high participant satisfaction ratings.

Conclusion

The LWTC programme facilitators displayed a satisfactory level of adherence to the protocol and a high level of competence in delivery. The level of fidelity established for the LWTC group-based education intervention is considered to be appropriate, and expected to provide some confidence to the interpretation of intervention outcomes and effectiveness.

1   BACKGROUND

1.1   Introduction

Since 2013, Westbank Community Health Care (CHC) and partner organisations have been delivering Living Well, Taking Control (LWTC), a community-based diabetes prevention and management programme. The core component of the LWTC programme involves a group-based education intervention that delivers a series of structured sessions, to promote sustainable healthy lifestyle changes for people with Impaired Glucose Regulation (also known as 'pre-diabetes' or non-diabetic hyperglycaemia) and those newly diagnosed with type 2 diabetes (T2D). This intervention was developed to meet evidence-based recommendations from the National Institute for Health and Care Excellence (NICE) Clinical Guideline 66 (CG66). The programme has on-going support that is also aligned to the Quality and Outcomes Framework (QOF), the Public Health Outcomes Framework, and the National Service Framework for Diabetes (Department of Health, 2001) where person-centred care is one of the central pillars. It is based around use of behaviour change processes and techniques that derive from self-regulation theories, such as the Social Cognitive Theory (Bandura, 1985) and Control Theory (Carver et al., 1982). These include goal setting, action planning, self-monitoring, progress feedback, problem solving, and reviewing goals.

Apart from being effective tools for self-management and support, group-based interventions have been shown to have significant benefits including improved fasting glucose levels, improved energy and improved emotional state (Trento, 2010; Holma, 2008). Adult education has been said by Trento et al. (2010, p. 747) to be 'a complex process and should not confine itself to providing information but educating on the whys'. Trento et al. also point out that in group environments, repeated peer discussions about problems and personal experiences improve their results. Transactional analysis theory backs this point by saying that adult-to-adult (as equals) discussions are far more beneficial in creating change than adult-to-child (telling) (Transactional analysis theory, Berne).

1.2   Fidelity of implementation

The current Fidelity of Implementation (FoI) study is part of a wider process evaluation of LWTC. Fidelity of implementation 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 a higher fidelity of implementation is associated with greater treatment effects (Durlak and DuPre, 2008; McIntyre et al., 2007). In the context of interventions implemented in community organisations, Fixsen et al. (2005) separated fidelity into two types: personnel fidelity (the implementation, i.e. delivery, of the actual intervention), and organisational fidelity (the implementation of intervention supports, such as training and coaching). Breitenstein, Gross, et al. (2010) believed it is important that researchers assess the perceived warmth and credibility of the facilitator, whether the same intervention is being delivered, and whether the treatment protocol is being adhered to (for content and dose). 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).

According to Dane and Schneider (1998), there are five aspects to the concept of fidelity – in the context of programme evaluation:
1. *Adherence* – that programme components are delivered as prescribed. *Did implementers do what was expected?*
2. *Exposure* – the amount of programme content received by participant. *Did participants receive as much as expected?*

3. *Quality of delivery* – the theory-based ideal in terms of processes and content. *Did implementers perform activities in the manner expected?*
4. *Participant responsiveness* – the engagement of the participants. *Did participants follow through as expected?*
5. *Programme differentiation* – that the unique features of the intervention are distinguishable from other programmes. *Did the treatment condition differ from the control condition as expected?*

Adherence refers to the extent to which practitioners' behaviours conform to the intervention protocol, measuring focus on the quantity or presence of prescribed behaviours defined in an intervention protocol, and evaluating those components specific and essential to the defined intervention (Breitenstein, Gross, et al., 2010). To measure exposure to programme content, attendance rates provided by intervention partners can be examined (Breitenstein, Gross, et al., 2010). The 'quality of delivery', otherwise known as competence, refers to how well the protocol is implemented and delivered, including qualities related to communication, technical abilities, and skills in responding to the participants receiving the intervention. Intervention context matters in the assessment of the generalisability of its effectiveness, and measurements of adherence and competence components should account for the context of the intervention setting. For example, in a group-based intervention, group members who monopolise the discussion test the facilitator's skill in keeping the other group members engaged while adhering to the intervention protocol.

Attaining and demonstrating intervention fidelity in evaluation research enables researchers to isolate the active ingredients of an intervention, determine its efficacy, 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 pose major obstacles to the development of new intervention methods (Bellg et al., 2004). Furthermore, non-systematic assessments of FoI can decrease the quality and usefulness of fidelity data (Nelson et al., 2012). Keller et al. (2009) reviewed several studies, finding that some attention was taken by researchers to address fidelity in intervention delivery, although none described how much of the intervention was delivered (exposure; Keller et al., 2009). There has also been great variation in how researchers conceptualise and measure FoI (Durlak and DuPre, 2008; Dusenbury et al., 2003), and researchers have employed a vast variety of terms (e.g., treatment integrity, adherence, competence, compliance; Nelson et al., 2012). Although some guidelines for fidelity assessment do exist, their usefulness is limited by their generality, often being developed based on literature from an array of fields, study types and contexts (Nelson et al., 2012). Nevertheless, fidelity analysis must be tailored to the intervention model, generally involve multiple sources of data, and be gathered by a diverse range of methods.

The most commonly reported methods used to collect fidelity data are:
- *Self-report methods* – Information collected directly from the practitioner or intervention participant. Data may be gathered using checklists or verbal reports. Practitioners are asked to indicate whether they implemented identified components of the intervention protocol.
- *In vivo and video observations* – Data is usually gathered via checklists and notes from the observations.
- *Audio recordings* – Data is usually gathered via checklists and notes from the observations.

Each of these data collection methods provides unique information regarding the adherent and competent implementation of an intervention. Researchers selecting a data collection method for FoI measurement should consider several factors including feasibility, cost, efficiency, reliability, reactivity, and the ability to collect adequate behaviour samples for measuring facilitator adherence and competence. The gold standard for measuring adherence to an intervention protocol is direct observation by trained third-party observers, and by video or audio recording (Horn et al., 2008; Miller and Mount, 2001). Direct observations provide the opportunity to give immediate feedback to intervention facilitators, thus quickly correcting errors, while video or audio recordings allow for more thorough observation of the intervention. Although there are fears

that direct observations and video recordings may be viewed as obtrusive, Hildebrand et al. (2012) assert that these methods did not negatively influence the results of their study.

Several barriers to maintaining fidelity in real life contexts have been identified. These include local adaptations of interventions, individual variations in facilitator adherence and competence, lack of available training and technical support, limited resources for supporting the intervention at the site level, and competing demands for the facilitators' time that can diminish their commitment or effectiveness (Breitenstein, Gross, et al., 2010). Lack of fidelity can weaken outcomes, leading to faulty conclusions about intervention effectiveness. Because they can cause potentially useful interventions to appear ineffective, failures in FoI have been identified as type III errors (Breitenstein, Gross, et al., 2010). To avoid a type III error, clear and feasible strategies for monitoring and measuring FoI should be delineated prior to initiation of an intervention study or dissemination efforts (Breitenstein, Gross, et al., 2010).

It is important to understand what 'delivered as intended' means in an FoI analysis, and to recognise that intervention integrity is more complex than simply providing the same training to each facilitator and the same dose of intervention to each participant (Kearney and Simonelli, 2006). Hawe et al. (2004) suggested that the form of complex interventions should be allowed to vary, while functions remain standardised; adaptations can be made while still retaining fidelity. The Centers for Disease Control and Prevention (CDC) use a traffic light system for intervention adaptations, where 'green' are safe adaptations, 'amber' are medium adaptations, and 'red' are adaptations that will lessen intervention effectiveness. In general, it is believed that interventions involve 'core components' i.e. those that cannot be changed, and other components that can be changed. However, if some components do not affect behaviour, and so can be changed, it brings about the question of why resources are being spent on them in the first place. The Medical Research Council (MRC) emphasises the need to capture fidelity, but the extent to which adaptations are permitted is a key dimension of complexity (Moore et al., 2015).

In line with MRC's recommendations for process evaluation, the FoI analysis and initial reporting were conducted prior to knowledge of outcomes effects to guard against interpretation bias. The purpose of analysing this data is not to produce a robust, in-depth qualitative analysis, but to provide sufficient feedback on the intervention to aid interpretation of quantitative findings and inform future refinements to the intervention and training materials. Analysis of raw audio recordings, rather than transcribed data is considered sufficient for this purpose.

1.3   Research aim

The aim of this study is to assess the fidelity of implementation of the LWTC programme, with a focus on facilitator adherence and competence.

2   METHODS

2.1   Study setting

The FoI study was conducted in four different facilities in Devon – three of these were in Exeter (i.e. Westbank CHC, Cardinal Newman House, and Exwick Community Centre), and one was in Tiverton (i.e. Sunningmead Community Centre). Although the intervention model was delivered across three locations outside Devon (Birmingham, Newcastle, and Darlington), these locations were unable to participate at the time, and thus excluded from the FoI assessment. Programme delivery in Devon was headed by Westbank.

2.2   Programme structure

Living Well, Taking Control has been developed by Health Exchange and Westbank as a community-based type 2 diabetes prevention and management programme. In 2013, the programme obtained funding as part of the Big Lottery Fund's Wellbeing Phase 2 initiative. This provided the opportunity to roll out the programme and refine its delivery in line with best practice guidance.
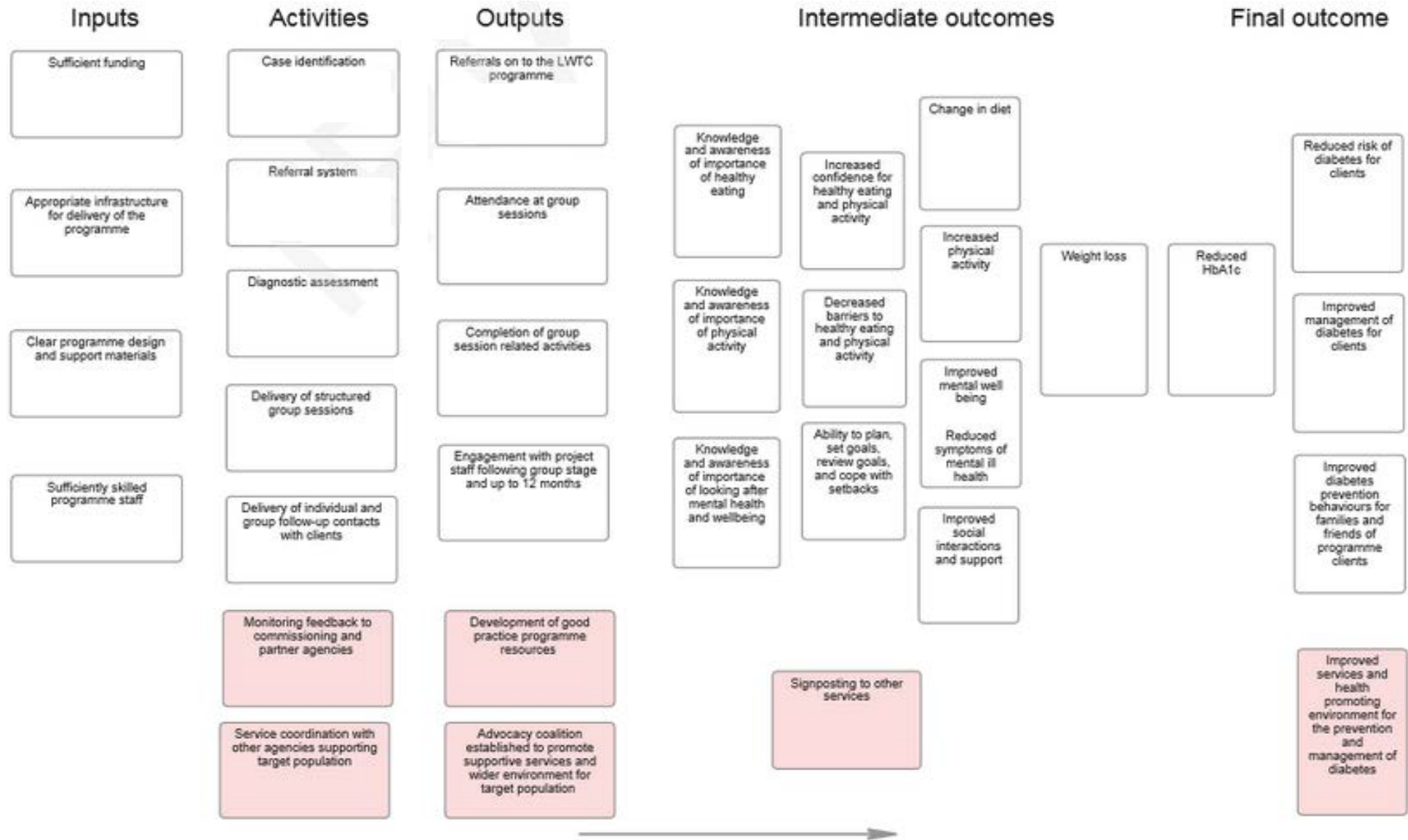
To ensure fidelity of the intervention, the programme partners developed standardised protocol manuals for Diabetes and 'Pre-diabetes' education to train and guide programme facilitators to use a person-centred, empathy-building approach to deliver comprehensive lifestyle advice. There were two facilitators recruited by Westbank, with different areas of expertise – one was in physical activity, while the other was in nutrition. In addition to the standardised Diabetes and 'Pre-diabetes' education training, the facilitators also underwent a Weight Management, Physical Activity and Behaviour Change course, which applies motivational interviewing (MI) techniques and self-directed behaviour change principles. Both facilitators have been delivering the programme since its initiation in November 2013, and so have had time to refine their expertise and techniques.

As per NICE recommendations, the programme aims to give participants at least 16 hours of contact time, either within a group, on a one-to-one basis, or using a mixture of both approaches. 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 biometric measures and a questionnaire. Then, four sessions are delivered over four weeks, each covering a different component: 'pre-diabetes'/T2D and a healthy lifestyle (one hour), healthy eating (2 hours), physical activity (2 hours), and positive mental health and wellbeing (2 hours).

At the end of the four-week programme, participants are asked to complete a feedback questionnaire that includes ratings of their satisfaction with the programme and the facilitators. They are then offered one-to-one or group follow-up sessions in months 2, 3, 6, 9, and 12 to review goals, changes and identification of any additional sessions focusing in more detail on certain aspects of the programme (nutrition, physical activity, and wellbeing), or given support through local community services (e.g. smoking cessation, alcohol reduction, health trainer). Biometric measures (weight, height, BMI, blood pressure, and HbA1C blood glucose levels) are taken prior to commencement of the programme i.e. baseline, on week 4 of the group sessions, and during the follow-up sessions at 2, 3, 6, 9 and 12 months. (Note: HbA1C is only taken at baseline, 6 months and 12 months).

Through discussions between the programme delivery team and the UWE evaluation team we developed a logic model to define the LWTC intervention in terms of the inputs, activities, outputs and intended outcomes. Figure 1 summarises this logic model and shows the central role of the group-based sessions in facilitating the programme outcomes.

Figure 1: Logic model depicting the LWTC intervention

Inputs	Activities	Outputs	Intermediate outcomes	Final outcome
Sufficient funding	Case identification	Referrals on to the LWTC programme	Knowledge and awareness of importance of healthy eating	Reduced risk of diabetes for clients
Appropriate infrastructure for delivery of the programme	Referral system	Attendance at group sessions	Increased confidence for healthy eating and physical activity — Change in diet	
Clear programme design and support materials	Diagnostic assessment	Completion of group session related activities	Knowledge and awareness of importance of physical activity — Decreased barriers to healthy eating and physical activity — Increased physical activity — Weight loss — Reduced HbA1c	Improved management of diabetes for clients
Sufficiently skilled programme staff	Delivery of structured group sessions	Engagement with project staff following group stage and up to 12 months	Improved mental well being	
	Delivery of individual and group follow-up contacts with clients		Knowledge and awareness of importance of looking after mental health and wellbeing — Ability to plan, set goals, review goals, and cope with setbacks — Reduced symptoms of mental ill health — Improved social interactions and support	Improved diabetes prevention behaviours for families and friends of programme clients
Monitoring feedback to commissioning and partner agencies		Development of good practice programme resources		
Service coordination with other agencies supporting target population		Advocacy coalition established to promote supportive services and wider environment for target population	Signposting to other services	Improved services and health promoting environment for the prevention and management of diabetes

2.3   Data collection

Fidelity of implementation was assessed primarily using audio recordings of programme group sessions, with the consent of participants. In order to prevent selection bias and ensure an adequate sample size, all sessions conducted by Westbank from 20th January to 5th March 2015 were audio recorded, either by the UWE researcher or by the facilitators, depending on session times and availability of the researcher. There were 5 'pre-diabetes' and 2 diabetes groups during this period, making up a total of 28 sessions, which is equivalent to 49 hours of audio recording. Consent was given for 100% of sessions that were approached, and none of the participants declined to participate; therefore, there was a good representative sample for this study.

Audio recorded data was supplemented by course satisfaction data obtained from participant feedback questionnaires, as a measure of facilitator competence.

2.4   Data analysis

Audio recordings were analysed by an independent rater, using a fidelity checklist that was developed to rate levels of implementation, and designed to enable the assessor to note down comments and/or themes emerging from the intervention delivery. Identification of fidelity criteria was guided by the standardised protocol manual and adapted according to the resources available at Westbank, upon agreement with the programme leader, with input from the facilitators. The initial checklist was piloted for 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 topics and 14 optional topics. The compulsory topics were further divided into the following criteria:

- Adherence – the extent to which facilitators conformed to the intervention protocol
- Competence – the skilfulness in the delivery of the intervention

The checklist topic configuration is shown in Table 1; a complete checklist is included in Appendix 1.

Table 1: LWTC fidelity checklist topic configuration

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

The level of implementation of each topic was rated as 'low/not observed', 'observed to a small degree', 'observed to a medium degree', or 'high implementation'. These were computed into an analysis spreadsheet. The sum of compulsory topics for each component was obtained by adding up the score for

each topic i.e. 'low/not observed' scored 1 point, 'observed to a small degree' scored 2 points, 'observed to a medium degree' scored 3 points, and 'high implementation' scored 4 points. The level of implementation score for each component was then calculated by dividing the sum of compulsory topics score by the number of compulsory topics. An overall level of implementation score for each group was calculated as an average of the scores from the four sessions. These scores were converted into percentages for a more universal presentation of outcomes. Although there is no actual agreement, from existing literature, as to what constitutes an acceptable level of implementation, the goal for this assessment was set at 80%.

2.5   Reliability and validity

To ensure reliability and internal consistency, ten percent of the audio-recorded intervention sessions were tested for inter-rater agreement (Mars T. et al., 2013). Two independent raters, both currently on the Masters in Public Health course, were recruited to analyse 5 hours of recordings each. An online random sequence generator was utilised to randomly select groups and sessions for analysis. Kappa statistics (κ) were calculated as an index of inter-rater agreement for compulsory adherence and competence topics, and interpreted using benchmarks published by Peat (2001): values less than 0.4 indicate poor agreement; 0.41–0.60, fair agreement; 0.61–0.80, good; and 0.81–1.00, very good agreement (Peat, 2001). P-values were also calculated as a test of whether the estimated kappa was not due to chance (Viera and Garrett, 2005).

2.6   Ethical issues

Facilitators were approached to gain permission to observe and record the sessions. Before the session started, everyone present (i.e. the facilitator, any volunteer, all participants and their partner or family member) was asked to provide verbal and written consent by signing and dating a consent form, to agree to take part in the FoI study and to give permission for anonymised data from the audio-recorded sessions to be used for the evaluation project. Participants were given the researcher's contact details and informed that they were free to withdraw from the study at any time, without affecting their right to continue with the LWTC programme. Participants were also made aware that their participation in the recorded sessions was entirely voluntary; they were free to refuse to answer any questions while the audio recording was running, and could request to listen to the audio recordings of the sessions at any time.

To ensure data anonymity and confidentiality, personal information from the audio-recordings is not included in any of the manuscripts or reports, instead, participants are referred to as 'the participant', and facilitators are referred to as 'the facilitator' or assigned alphabetical identifiers, i.e. 'Facilitator A' or 'Facilitator B' . Although we recognise that there are two different facilitators, this study was not aimed as a comparison exercise between them and therefore, results will not indicate which sessions were conducted by which facilitators. Ethical approval for the study was obtained from the UWE HAS Research Ethics Committee.

3   FINDINGS

3.1   Participant characteristics

Information from audio recordings was cross-checked with the number of consent forms received – there were 49 participants in the FoI analysis across the seven groups that received the intervention during the study period. Table 2 shows a breakdown of the number of participants per group, and includes any partners or family members who were consistently present to provide support during sessions.

Table 2: Size of fidelity groups – includes number of participants, and partners or family members

Group ID (P – 'pre-diabetes'; D – diabetes)	No. of participants	No. of partners/family members
P31	8	0
P32	7	2
P33	7	1
P34	9	3
P35	8	1
D20	7	1
D21	3	1

T-tests were conducted to see if there were any significant differences between the participant characteristics of the FoI study sample compared to the wider Westbank sample. This was done using information from the questionnaire that participants completed as part of the wider service evaluation, which was available for only 46 participants. The slight difference in number was not expected to have any significant effect on the t-tests. Results of these are summarised in Table 3.

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

Participant characteristics		Fidelity groups	Overall Westbank group	p-value
Age range		39-80 years	28-91 years	
Diagnosis	'Pre-diabetic'	80.4%	68.2%	p=0.49
	Diabetic	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

There was no difference between the groups except for the following characteristics:
- Participants in the fidelity groups were significantly heavier than the overall Westbank participants (p<0.05)
- Participants in the fidelity groups had a significantly lower HbA1c than the overall Westbank participants (p<0.05)
- The overall Westbank participants had a significantly higher education level than participants in the fidelity groups (p<0.05)

Exposure to the programme content was reflected in the attendance rates at each session, or the number of sessions attended by each participant – these are detailed in Table 4.

Table 4: Attendance rate for fidelity groups – a measure of exposure to programme content

Attendance rate, % (number of participants, n)			
Session	**Exposure**	**No. of sessions**	**Exposure**
Session 1	100% (46)	4 sessions	63.04% (29)
Session 2	84.78% (39)	3 sessions	21.74% (10)
Session 3	78.26% (36)	2 sessions	6.52% (3)
Session 4	76.09% (35)	1 session	8.7% (4)

3.2 General observations and overall impression of group dynamics

While formal data was not collected to assess intervention context, the following general observations were made from audio recordings (observations on group dynamics received additional input from the independent raters recruited for the inter-rater agreement test):

Group dynamics
- *Facilitators*
  - Professional, diplomatic, very calm and patient; all questions were handled well with good explanations
  - Encouraged group participation from the start of the sessions and was effective in ensuring the whole group was engaged, prompting the quieter ones to participate in discussions

- Encouraged participants to share ideas and support each other in making changes, reminding them that confidentiality would be maintained
- Supportive of participants who were negative, demotivated, or less confident in making healthy lifestyle changes
- *Participants*
  - Good group dynamics across all groups – participants settled comfortably, with good overall contribution to the discussions, and were supportive of one another.
  - Several groups started off rather quiet, but participants eventually became more at ease with one another towards the end of the first session, which increased participation.
  - Some participants thought they ate well or did enough physical activity.
  - Participants took their health issues seriously and were willing to do everything possible on their part to change and maintain a healthy lifestyle.
  - Participants were happy with the programme and expressed their gratitude to the facilitator.
  - The facilitator described group D20 as *"well-informed"* and *"well-read"*, and expressed that *"time always ran away"* with this group. This was quite a difficult group at times and possibly very stuck in their ways. Session topics jumped around a bit depending on where the group conversations went, but they seemed to be worthwhile conversations the majority of the time.
  - Group D21 was comparatively small and everyone, including the participant's daughter, actively participated in the discussions. One 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 organiser.

Facilitators' use of different intervention delivery tools or activities

Table 5: Intervention delivery tools used by facilitators

Facilitator	Topics discussed/explored in group task	Tools used	Implementation
A	Overview of what diabetes/pre-diabetes is, and its associated symptoms	Video (also used by Diabetes UK)	2 pre-diabetes groups; 1 diabetes group
	Energy balance	Flipchart paper	1 pre-diabetes group
	Relaxation/de-stressing techniques; positive and negative coping strategies	Post-it notes	2 pre-diabetes groups
B	Understanding of healthy eating	Flipchart paper	3 pre-diabetes groups
	Benefits of physical activity (statistics)	Video	1 pre-diabetes group
Both	Benefits of physical activity	Flipchart paper	5 pre-diabetes groups; 1 diabetes group

- These activities were creative, encouraged group interaction, improved understanding and retention of information, and gave motivation. Videos were used depending on technical capabilities available on location.
- Both facilitators engaged participants in all groups in an activity ('sugar game') around food labelling – participants were asked to arrange various products according to how much sugar they thought each contained. While Facilitator B simply revealed the actual amount of sugar content stated on the labels, Facilitator A asked one volunteer to weigh out the amounts using a scale. The method used by Facilitator A was more time-consuming, but provided a better illustration.
- Facilitator A taught the 'pre-diabetes' group that met at Westbank (where facilities and equipment were available) some seated exercises. There was good participation and participants seemed to enjoy themselves, while learning and doing the exercises.

Advice on media influence
- *Newspapers*
All groups tended to bring up the issue of health advice or research findings reported in the newspapers at some point during the 4-week programme, asking how reliable they were. The facilitators highlighted that the advice offered on the programme was based on the NICE Guidance, while media reporting was not usually accurate or evidence-based. Therefore, they should be careful of media headlines and propaganda, and not to believe everything that is being reported.
- *Cooking programmes*
Several groups also mentioned cooking programmes, asking whether their recommendations were worth following. The facilitators pointed out that such programmes were aimed at marketing tasty recipes, which were not necessarily healthy. They advised participants to be careful when considering whether or not to replicate the recipes exactly.

Issues beyond the facilitator's control or beyond the scope of the programme
- A 'pre-diabetic' participant brought up the issue that the Westbank gym was too busy in the mornings. She had osteoporosis and was only able to use certain machines, which were often occupied by people she did not feel comfortable approaching. The facilitator informed that rehabilitation programmes were also carried out at the gym in the morning, which contributes to it being busy. However, this problem was beyond her control.
- There was a rather lengthy discussion about diabetes medication in one of the diabetic groups. Participants were advised to mention these concerns to their general practitioner (GP) or diabetes nurse, as it was not within the scope of the programme.

Other observations
- In all groups, no reference was made to the stages of change model when exploring benefits and challenges to change.
- There was an overall high degree of dialogue with only a small amount of didactic time.
- The occasional late-comer or early-leaver caused minimal interruption to the sessions.

3.3   Adherence to intervention protocol

The results of the data analysis for adherence to the LWTC intervention protocol are shown in Table 6. The recording of Session 1 for group P32 was incomplete due to audio recorder dysfunction, but calculation of scores have been adjusted to take this into account so that unbiased comparisons can still be made across all groups. Inter-rater agreement for adherence criteria was found to be moderate ($\kappa = 0.60$, $p<0.00$).

Table 6: Level of implementation scores for adherence criteria

Group ID	Level of implementation scores for adherence topics				Overall level of implementation score
	Session 1	Session 2	Session 3	Session 4	
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
D20	3.45	2.62	3.09	2.31	2.83
D21	2.82	2.77	2.82	2.46	2.71
Average	**3.50**	**2.96**	**3.39**	**2.65**	**3.09**
	87.43%	**73.93%**	**84.79%**	**66.25%**	**77.32%**

Generally, the 'pre-diabetes' groups scored higher than the diabetes groups in all sessions. Sessions 1 and 3 exceeded the 80% threshold of implementation acceptability for this assessment. Topics that were rated as 'high implementation' for all groups are listed in Table 7.

Table 7: Highly implemented adherence criteria for Sessions 1 – 3

Session 1	• Assess importance and confidence in making healthy lifestyle changes • Overview of what diabetes/'pre-diabetes' is • Introduce the 5 key healthy lifestyle messages • Explain clinical metrics
Session 2	• Assess group and individual understanding of healthy eating • Assess importance and confidence to make healthy dietary changes • 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 • Food labelling
Session 3	• Assess importance and confidence to increase physical activity • Introduce the physical activity guidelines • Discuss the benefits of physical activity, and the different types of activity

Session 4, which focuses 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, and these are summarised in Table 8.

Table 8: Summary of adherence criteria commonly omitted or implemented at a low level

Comprehension and retention of information	• Recap and assess retention from previous week's session • Review all topics at the end of Session 4
Activity diaries	• 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	• Introduction to the concept of positive thinking • Importance and confidence to maintain healthy emotional wellbeing • Barriers to positive thinking
Goal setting	• Review goals set, and set new goals for future

3.4   Competence in intervention delivery

Table 9 shows that the overall level of implementation scores ranged from 3.71 (92.75%) to 3.93 (98.25%), which indicates a high level of competence across all groups. There was good inter-rater agreement for competence criteria ($\kappa = 0.71$, $p<0.00$). Facilitators did not achieve full implementation scores for Session 1, most commonly due to omission of the confidentiality agreement.

Table 9: Level of implementation scores for competence criteria

Group ID	Level of implementation scores for competence topics				Overall level of implementation score
	Session 1	Session 2	Session 3	Session 4	
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
Average	**3.44**	**4.00**	**4.00**	**4.00**	**3.81**
	85.89%	**100.00%**	**100.00%**	**100.00%**	**95.14%**

Course satisfaction data was available for 31 out of the 49 participants (63.3%). The other participants did not complete the feedback questionnaire at this point of the programme delivery. A summary of the data is shown in Table 10. Overall, the participants had high satisfaction ratings of the LWTC programme, which affirms facilitator competence in intervention delivery.

Table 10: Summary of course satisfaction data

Question	Response, % (n)		Statistics
Did the course benefit you?	Yes	96.8% (30)	
	Missing	3.2% (1)	
How much did you enjoy the course?	10	48.4% (15)	Mean 9.13
[Rated on a score of 1-10; 1 being the worst score and 10 being the best]	9	19.4% (6)	SD 0.96
	8	29.0% (9)	Range 7-10
	7	3.2% (1)	
Did it meet your needs?	Yes	96.8% (30)	
	Missing*	3.2% (1)	
Would you recommend to your family and friends?	10	54.8% (17)	Mean 9.23
[Rated on a score of 0-10; 0 being the worst score and 10 being the best]	9	22.6% (7)	SD 1.17
	8	12.9% (4)	Range 5-10
	7	3.2% (1)	
	5	3.2% (1)	
	Missing	3.2% (1)	

*When asked why, the participant said that it was *"difficult to say due to my disability"*.

3.5   Implementation of optional topics

The overall percentage of optional topics implemented ranged from 45.45% to 63.64% across all groups. Optional topics that were always implemented were offering refreshments and repeating clinical metrics. The optional walk or seated exercise in Session 3 was only done for one group, while relaxation exercise in Session 4 was never done. 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 topics for diabetic patients: expectations from healthcare professional, information about annual reviews, and the 15 Healthcare Essentials – none of these were implemented for either group.

4 DISCUSSION

Results of the t-test (Table 3) suggest that the FoI study sample was largely representative of the wider Westbank programme participant population. This suggests that the group sessions were delivered to typical sample of participants taking part in the programme, which allows the intervention outcomes to be generalised to a certain degree.

Calculation of the overall level of implementation score for adherence criteria, for only the 'pre-diabetes' groups, resulted in an average of 80.55 %, which is considered an acceptable level of adherence. Although the facilitator seemed to encounter some difficulty in maintaining a high level of adherence to the intervention protocol when conducting sessions with the diabetes groups (average of 69.25%), she was still able to demonstrate a relatively high level of competence. For the diabetes groups, the challenge for the facilitator might have been to balance between addressing participants' questions during discussions while still adhering to the protocol, within the time allocated for each session.

Session 4 had the lowest attendance rate (76.09%), i.e. participants were least exposed to the positive mental health and wellbeing content of the programme, and this session also had the lowest level of implementation score (66.25%). Audio recordings reveal that the different backgrounds of the facilitators, i.e. physical activity and nutrition, had some influence on the amount of emphasis they placed on each of those two aspects of the programme, although it is not reflected in the level of implementation scores. As far as the researchers are aware, neither of the facilitators received training in the area of positive mental health and wellbeing, which might have affected their confidence in delivering this particular component. Since evidence suggests that this is a crucial factor 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 or the lack of exposure would affect intervention effectiveness.

Activity diaries were not reviewed in all groups 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 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. 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. 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.

Even though everyone present at the sessions were required to provide verbal and written consent at the very beginning, the 'confidentiality agreement' criterion was included in the checklist as 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. This criterion was not heard mentioned in four out of the seven groups, and was therefore scored as 'not observed', but it may be assumed to have been implemented prior to the recorder being turned on, when the participants were asked to provide consent.

The p-values obtained from the statistical calculations show that the inter-rater agreement observed for both adherence and competence criteria was not due to chance (p<0.00). Several scores given by the two independent raters recruited for the inter-rater agreement test were overruled by the principle rater after consultation with the senior researcher. 'Friendly welcome' was scored as 'low/not observed'. However, an assumption was made that this was always done prior to starting the recorder, and therefore the overruling score was 'high implementation'. In the audio recordings analysed for inter-rater agreement, two of the

adherence topics related to healthy eating were only briefly mentioned in Session 2, but were discussed more in depth in Session 3. Since the second raters were not required to analyse the corresponding Session 3 for those groups, they were unable to accurately score those criteria; therefore, the overruling score was 'high implementation'.

There were seven adherence topics that were scored as 'low/not observed' by the principle rater, but scored as 'high implementation' by the second rater (Rater A). After re-examination of recordings of the relevant sessions, the principle rater has maintained her scoring decisions. Following a discussion with the second raters, the principle rater is of the opinion that Rater A was not as accurate in identifying information from the audio recordings as Rater B, and that Rater A also had a different understanding of some of the criteria. A decision was made to overrule these extreme differences in scoring in favour of the principle rater. These impressions of Rater A, as well as Rater B being stricter in her scoring than the principle rater (i.e. often scored one step lower than the principle rater), might account for the moderate agreement obtained for adherence criteria.

The optional walk or seated exercise was only done for one group, which was a 'pre-diabetic' group, carried out by the facilitator whose expertise was in physical activity. There are several possible reasons that could explain why this activity was not implemented more often: suitable equipment was not available on location, lack of facilitator expertise, or insufficient time. These latter two reasons might also be why the relaxation exercise and optional topics specifically for diabetic patients were not implemented.

4.1   Strengths of the study

The method of data analysis was mainly quantitative, with a supplementary thematic analysis that was useful to provide some insight into the intervention context. There were several advantages to using audio recorders for data collection – they were small and relatively unobtrusive, produced good sound quality, and were less costly than observations. Audio recording was non-intrusive, thereby reducing potential reactivity effects. Audio recordings allowed both adherence and competence to be evaluated because the independent rater could hear not only what was said but how it was said. They also allowed for re-examination of the intervention sessions and analysis of reliability among fidelity raters.

4.2   Limitations of the study

Despite the aforementioned benefits, audio recordings could not capture certain types of communication, such as non-verbal cues, and did not allow for assessment of environmental factors that may be important to adherence and competence ratings (e.g., cramped intervention site, extraneous events that distract participants). The researcher also encountered a couple of other issues with audio recordings – facilitators forgot to start the recorder running at the start of the session, and occurrence of equipment malfunction at one of the sessions.

Although results show a high overall level of implementation and good inter-rater agreement for the competence criteria, the accuracy of competence ratings is questionable due to a lack of experience and training on the part of the raters. In addition, the fidelity checklist might not be sufficiently robust to assess facilitator competence.

4.3 Recommendations

In order to improve adherence and quality of delivery with regards to the 'positive mental health and wellbeing' component of the intervention, it is recommended to review the programme protocol to give clearer guidance and enhance facilitator training in that area. A more robust method of assessing facilitator competence may need to be implemented, such as the use of a six-point Likert scale that incorporates the Dreyfus system (Dreyfus, 1989) for denoting competence.

Robust and in-depth qualitative analysis of pre-existing data collected from interviews and focus groups should be carried out to provide a more comprehensive understanding of the implementation of this intervention. It would also be useful for future research to assess the impact that group size, group dynamics and age differences between participants within a group have on the fidelity of group-based interventions.

5   CONCLUSION

In conclusion, an appropriate level of fidelity was established for the LWTC group-based education intervention – facilitators displayed 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 fidelity would have been more desirable to increase confidence in the interpretation of intervention outcomes and effectiveness. The eventual outcomes will help to determine if components that were omitted or implemented at a low level were crucial to ensuring effectiveness of the intervention, and if not, they will need to be reviewed or removed from the protocol.

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APPENDIX 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: Topics not highlighted are 'adherence' criteria; topics highlighted orange are 'competence' criteria; topics 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: Topics not highlighted are 'adherence' criteria; topics highlighted orange are 'competence' criteria; topics 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					
Diabetic patients only Expectations from your health care professional (what to expect from your GP, practice nurse etc)					
Diabetic patients only Annual Reviews (e.g., what is included? How often? What will happen?)					
Diabetic patients only 15 Healthcare Essentials					

Note: Topics not highlighted are 'adherence' criteria; topics highlighted orange are 'competence' criteria; topics 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: Topics not highlighted are 'adherence' criteria; topics highlighted orange are 'competence' criteria; topics highlighted grey are optional.