Evaluating the fidelity of implementation of a voluntary sector-led, community-based diabetes prevention and management programme

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INTRODUCTION

- **Living Well, Taking Control (LWTC)** is a community-based type 2 diabetes (T2D) prevention and management programme:
  - Objective: To promote sustainable healthy lifestyle changes
  - Target population: People with pre-diabetes & newly-diagnosed T2D
  - Core component of intervention: Group-based structured education sessions delivered weekly, for 4 weeks, by trained facilitators
- This intervention was designed to meet evidence-based recommendations from NICE[1].
- The clinical and cost effectiveness of the diabetes prevention component of LWTC is being evaluated in the **ComPoD trial**.
- The Fidelity of Implementation (FoI) Study is part of a wider service evaluation of LWTC, and is critical to successful translation of evidence-based interventions into practice.
- The heart of fidelity is often considered to be intervention delivery, whose core components are adherence and competence[2,3]:
  - **Adherence –** extent to which facilitators conform to the intervention protocol
  - **Competence –** skilfulness in the delivery of the intervention

AIM: To assess the fidelity of implementation of the LWTC programme, with a focus on facilitator adherence and competence.

METHODS

STUDY SETTING

- Four facilities in **Devon**: 3 in Exeter, 1 in Tiverton
- Programme delivered by the voluntary-sector organisation, **Westbank**

DATA COLLECTION

- Audio recording of sessions conducted from 20 January to 5 March 2015
  - 5 pre-diabetes and 2 diabetes groups (total of 49 participants)
  - 28 sessions = 49 hours of audio recording
- Course satisfaction data was used to support findings on competence

DATA ANALYSIS

- Audio recordings were analysed using a **fidelity checklist**
- The **level of implementation** for each item was rated: Low/not observed (1 point); Observed to a small degree (2 points); Observed to a medium degree (3 points); High implementation (4 points)
- The level of implementation score for each component
  = Sum of compulsory items score / Number of compulsory items
- Overall level of implementation score for each group
  = Average of the scores from the four sessions
- The goal for an acceptable level of implementation was set at 80%
- 10% recordings tested with Kappa statistics (κ)[4] for inter-rater agreement

Session: Programme component	No. of compulsory items	No. of optional items
1: Pre-diabetes/T2D & 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 diabetic participants only)
4: Positive mental health & wellbeing	Adherence items: 13 Competence items: 3 Total: 16	5

Table 1: LWTC fidelity checklist item configuration

RESULTS

PARTICIPANT CHARACTERISTICS

- Using questionnaire data, 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.
- There were no significant differences between the groups except for the following characteristics:
  - Participants in the fidelity groups were significantly heavier ($p<0.05$) but had a significantly lower HbA1c ($p<0.05$) than the overall Westbank participants.
  - The overall Westbank participants had a significantly higher education level than participants in the fidelity groups ($p<0.05$).

ADHERENCE

- Examples of adherence items on the fidelity checklist:
  - Assess importance & confidence in making healthy lifestyle changes
  - Goal-setting or review goals set

Group ID [Pre-diabetes (P); Diabetes (D)]	Level of implementation scores for adherence items (on a scale of 0-4)				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
Mean	3.50	2.96	3.39	2.65	3.09
	87.43%	**73.93%**	**84.79%**	**66.25%**	**77.32%**

Table 2: Level of implementation scores for adherence criteria

- The mean overall level of implementation score for adherence to intervention protocol was 77.32%.
- Inter-rater agreement was moderate ($\kappa = 0.60$, $p<0.001$).
- Generally, scores for pre-diabetes groups were higher than diabetes groups for all sessions.
- Scores for Session 4 were consistently the lowest for all groups.

COMPETENCE

- Examples of competence items on the fidelity checklist:
  - Opportunity for participants to ask questions
  - Opportunity & encouragement for participant-led group discussion
- The overall level of implementation scores ranged from 3.71 (92.75%) to 3.93 (98.25%), indicating a high level of competence across all groups.
- There was good inter-rater agreement ($\kappa = 0.71$, $p<0.001$).
- Facilitators did not achieve full implementation scores for Session 1, most commonly due to omission of the 'confidentiality agreement' criterion.
- Overall, the course satisfaction data showed that participants had high satisfaction ratings of the LWTC programme, which affirms facilitator competence in intervention delivery.

Group ID [Pre-diabetes (P); Diabetes (D)]	Level of implementation scores for competence items (on a scale of 0-4)				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
Mean	3.44	4.00	4.00	4.00	3.81
	85.89%	**100%**	**100%**	**100%**	**95.14%**

Table 3: Level of implementation scores for competence criteria

IMPLEMENTATION OF OPTIONAL ITEMS

- The overall percentage of optional items implemented ranged from 45.45% to 63.64% across all groups.
- 'Offering refreshments' and 'Repeating clinical metrics' were always implemented.
- The optional walk or seated exercise in Session 3 was implemented for one group.
- The optional relaxation exercise in Session 4 was never implemented.
- Signposting to healthcare professionals, local services, or additional support were carried out as required.
- None of the three additional optional items for diabetic participants were implemented, i.e. expectations from healthcare professional, information about annual reviews, and the 15 Healthcare Essentials.

OVERALL IMPRESSION OF GROUP DYNAMICS

General observations of group dynamics from the audio recordings:

Facilitators

- Professional; patient; handled questions well, with good explanations
- Effectively encouraged group participation and engagement
- Encouraged participants to share ideas and support each other in making changes
- Supportive of participants who were negative, demotivated, or less confident in making healthy lifestyle changes

Participants

- Good overall contribution to the discussions; supportive of one another
- Several groups were fairly quiet at the start, but became more talkative towards the end of Session 1
- The facilitator described group D20 as *"well-informed"* and *"well-read"*, and expressed that *"time always ran away"* with this group.
- Group D21 was comparatively small and everyone 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 organisation.

DISCUSSION

- Results suggest that the group sessions were delivered to a typical sample of programme participants, which allows the intervention outcomes to be generalised, to a certain degree, to the wider Westbank sample.
- It might have been challenging for the facilitator to address all the diabetic participants' questions within the allocated time of the session, while still adhering to the protocol.
- Neither facilitator had previous training in mental health and wellbeing support, which may have affected confidence in delivering Session 4.
- The moderate inter-rater agreement for the adherence criteria, may be due to the raters having varying interpretations of some of the criteria.
- All participants were required to provide consent at the start of Session 1. The 'confidentiality agreement' criterion was a measure of facilitators' competence in creating an open and safe environment – it may be assumed to have been implemented prior to the recorder being turned on.
- Lack of local facilities, facilitator expertise, or time, are possible reasons why optional activities/items were not implemented more often.
- It is recommended to review the programme protocol 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.
- A more robust method of assessing facilitator competence may need to be implemented.

CONCLUSION

- The LWTC programme facilitators displayed a satisfactory level of adherence and a high level of competence.
- The level of fidelity established for the LWTC group-based education intervention is considered appropriate, and will provide some confidence in findings related to intervention effectiveness.
- The study demonstrated the viability and value of measuring fidelity in a voluntary sector-led public health initiative.

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