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ARTICLE

Intervention fidelity assessment: A sub-study of the Norfolk Diabetes Prevention Study (NDPS)

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Abstract

Background: Previous research has shown that lifestyle modification can delay or prevent the onset of type 2 diabetes in high-risk individuals. The Norfolk Diabetes Prevention Study (NDPS) was a parallel, three-arm, randomized controlled trial with up to 46 months follow-up that tested a group-delivered, theory-based lifestyle intervention to reduce the incidence of type 2 diabetes in high-risk groups. The current study aimed to evaluate if the NDPS intervention was delivered to an acceptable standard and if any part(s) of the delivery required improvement.

Methods: A sub-sample of 30, 25 for inter-rater reliability and audio-recordings of the NDPS intervention education sessions were assessed independently by two reviewers (CT, TW) using a 12-item checklist. Each item was scored on a 0–5 scale, with a score of 3 being defined as 'adequate delivery'. Inter-rater reliability was assessed. Analysis of covariance (ANCOVA) was used to assess changes in intervention fidelity as the facilitators gained experience.

Results: Inter-rater agreement was acceptable (86%). A mean score of 3.47 (SD = .38) was achieved across all items of the fidelity checklist and across all intervention facilitators (n = 6). There was an apparent trend for intervention fidelity scores to decrease with experience; however, this trend was non-significant ($p > .05$) across all domains in this small sample.

Conclusion: The NDPS was delivered to an acceptable standard by all Diabetes Prevention Facilitators. Further research is needed to better understand how the intervention's

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delivery characteristics can be optimized and how they might vary over time.

KEYWORDS
behaviour change, intervention fidelity, lifestyle intervention, NDPS, type 2 diabetes

Statement of Contributions

- This paper identifies that for this intervention, at least, intervention fidelity does not appear to decrease significantly when intervention facilitator experience increases. It also shows the need for further research exploring how intervention delivery may or may not affect trial delivery. The findings from this paper add clarity to the debate of how can you ensure acceptable intervention fidelity when delivering a complex intervention both in the area of diabetes prevention and more widely.

BACKGROUND

Diabetes affects 3.9 million people in the United Kingdom this is predicted to increase to 5.3 million by 2025 if current practices remain unchanged, of whom 90% are diagnosed with type 2 diabetes (Diabetes UK, 2019). The personal and healthcare costs of type 2 diabetes are substantial, with the National Health Service (NHS) spending approximately 9% of its budget (£9 billion) on type 2 diabetes each year (Diabetes UK, 2014).

Weight, healthy eating and physical activity are regarded as key modifiable risk factors to reduce transition rates from high risk of developing type 2 diabetes to type 2 diabetes (Davies et al., 2004; Sampson et al., 2021; Yates et al., 2014). Lifestyle interventions that address these risk factors can delay or even prevent the onset of type 2 diabetes in high-risk individuals (Knowler et al., 2002; Lindström et al., 2003; Tuomilehto et al., 2001). Successful lifestyle interventions are associated with a 40%–58% relative risk reduction in transition rates (Gillies et al., 2007; Knowler et al., 2002; Lindström et al., 2006; Sampson et al., 2021).

The Norfolk Diabetes Prevention Study (NDPS) was a large-scale randomized trial (UK National Institute for Health Research (NIHR) RP PG 0109–10013). The study aimed to reduce the incidence of type 2 diabetes in high-risk groups and improve glycaemic control in people with newly diagnosed screen detected type 2 diabetes in a real-world UK healthcare setting (Sampson et al., 2021). The sequence of measures and delivery of intervention sessions is summarized in Figure 1. The protocol, baseline papers, and results from the NDPS trial are published elsewhere (Garner et al., 2022; Pascale et al., 2017; Sampson et al., 2018, 2021). The NDPS identified people with high-risk intermediate glycaemic categories (i.e. at high of diabetes) in the East of England and following screening, and eligible participants entered a randomized three-arm parallel group trial with up to 46 months of follow-up. This evaluated the effectiveness of a group-delivered, theory-based lifestyle intervention, delivered by a Diabetes Prevention Facilitator, with or without the support of trained lay volunteers who had type 2 diabetes.

The NDPS lifestyle intervention was developed using the Process Model of Lifestyle Behaviour Change (Artinian et al., 2010; Greaves et al., 2010), a theory of health behaviour change adapted from the Health Action Process Approach (Greaves, 2012; Schwarzer, 2014). The key intervention processes were (i) increasing motivation and social support; (ii) making a specific action plan and (iii) supporting maintenance through repeated 'self-regulatory cycles' of planning, self-monitoring and other feedback, problem solving to manage setbacks and revision of action plans. There was also an emphasis on empowering

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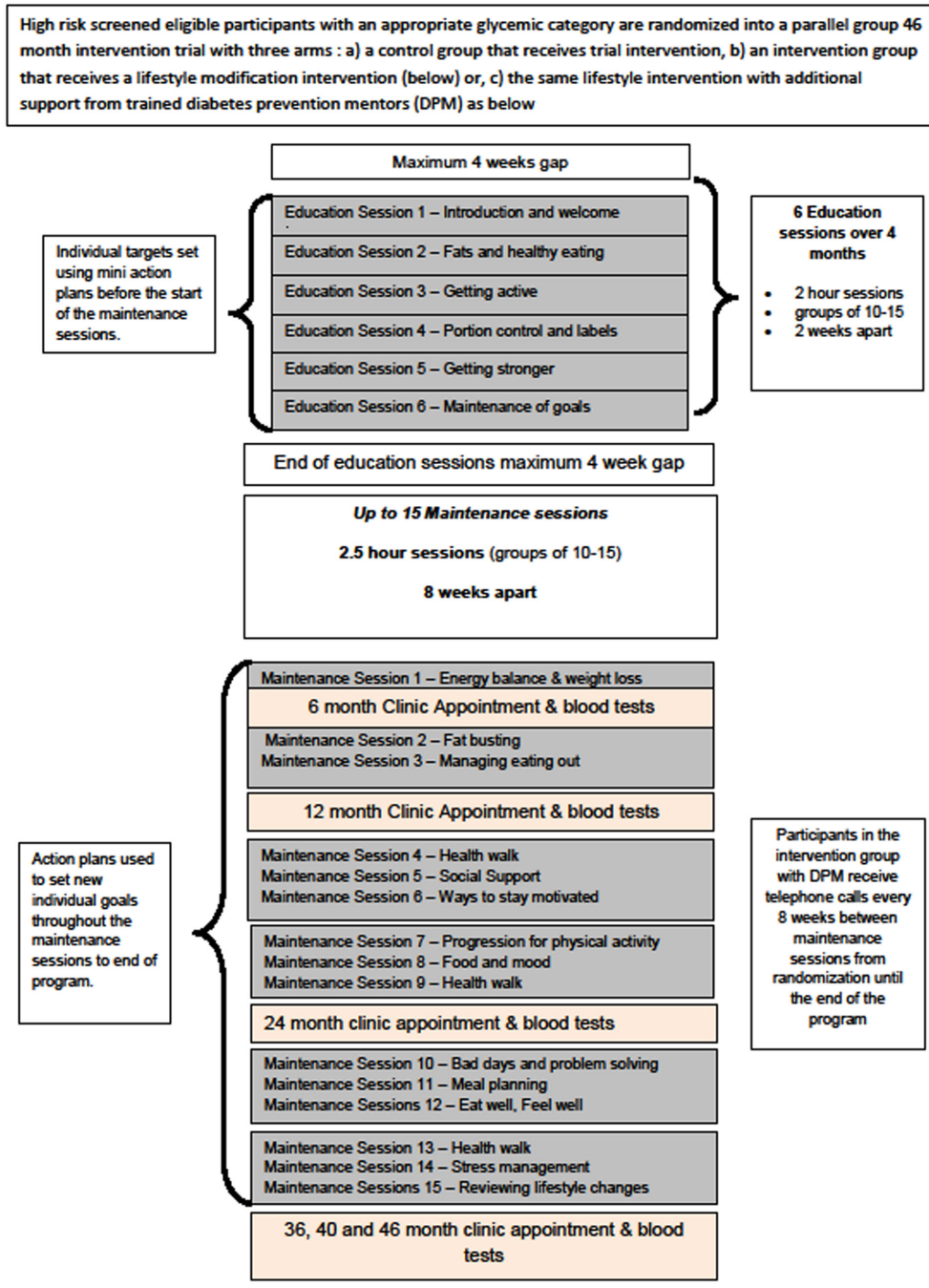

FIGURE 1 The Norfolk Diabetes Prevention Study: Timing of intervention sessions and measures. The control group received a one-off education session, the data from these sessions are not included in this study.

participants to develop autonomous motivation and to 'make changes you can live with' to ensure that plans for lifestyle change were sustainable. The NDPS intervention comprised six two-hour 'core' educational group sessions of varying content for the first 12 weeks after randomisation, followed by maintenance sessions eight weeks apart from month 4 until the end of the study, a maximum of 15. Maintenance sessions were discussion based, beginning with a 50-min supervised physical activity/muscle-strengthening

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exercise session. Sessions contained no more than 15 participants. A detailed description of the intervention is available elsewhere (Pascale et al., 2017). The results for the main trial have been reported previously (Sampson et al., 2021). In short, they showed the NDPS intervention was highly effective. Reducing the chances of progressing to type 2 diabetes over a mean 25-month follow-up by 43% (with similar performance for both intervention arms).

Group-based behaviour change interventions are complex and require skilled facilitation to ensure successful delivery and tailoring of all their components (Craig et al., 2008) and management of complex interpersonal dynamics within the group (Borek et al., 2019). Behavioural interventions may fail to be effective due to poor fidelity of delivery (Dusenbury et al., 2003), i.e. the intended programme was not delivered as intended by the developers. Hence, it is important to assess the fidelity of intervention delivery as part of their evaluation (Moore et al., 2015; Toomey et al., 2020). Intervention fidelity refers to the reliability and validity of behavioural interventions, including fidelity of intervention design and training to the intended theoretical mechanisms (design fidelity and training fidelity), quality of intervention delivery (delivery fidelity), intervention receipt and enactment of skills taught by the intervention (Bellg et al., 2004). Although there is increasing interest in intervention fidelity assessment (Hawkes et al., 2021; Lambert et al., 2017; Thompson et al., 2018), this is an area that remains under-investigated particularly in the field of diabetes self-management and prevention (Schinckus et al., 2014). Furthermore, fidelity assessment can provide insights that help to refine behavioural interventions for future implementation (Daw et al., 2020; Dusenbury et al., 2003; Frost et al., 2019). The specific aims of this sub-study of the main NDPS trial were to

i. assess the delivery fidelity of the core sessions of the NDPS intervention.
ii. assess whether delivery fidelity in the core sessions changed over time, as the experience of the facilitators in delivering the programme increased.

METHODS

A retrospective observational study was undertaken to examine the intervention fidelity of the six 'core' educational sessions in the NDPS intervention. All methods were carried out in accordance with the relevant guidelines, and informed consent was obtained from all participants. The NDPS study was given a favourable ethical opinion on the 3rd January 2011 by the NRES committee East of England Essex (REC number: 10/H0301/55).The fidelity assessment was specified a priori elsewhere (Pascale et al., 2017).

Participants

Adults aged 40 years who are either at high risk of developing or have newly diagnosed type 2 diabetes who were randomized into either of the intervention arms of the NDPS (with or without a diabetes prevention mentor). An in-depth definition of participant eligibility can be found elsewhere (Pascale et al., 2017).

Diabetes prevention facilitators (DPFs)

All DPFs attended a training course delivered over seven 120–150 min sessions over a minimum of 4 weeks to allow time for self-reflection and reading between each session. All DPFs were healthcare professionals but to be able to facilitate sessions they needed to demonstrate an understanding of the intervention theory and to demonstrate successfully the active listening skills required, a more detailed description is given elsewhere (Pascale et al., 2017).

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Sampling

All of the 'core' education sessions delivered in the NDPS were recorded. A total of 30 audio recordings were selected for analysis to provide a sample of five audio recordings for each of the six Diabetes Prevention Facilitators (DPFs) who delivered the core sessions. The following criteria were used to select five sessions for each of the six DPFs: (a) recording quality (the recording was of reasonable quality, with the majority of the facilitator speech being audible), (b) a balanced mix of the six 'core' Education sessions, and (c) sessions recorded were in consecutive years where possible to allow tracking of changes in fidelity over time. DPFs had the opportunity to decline to be recorded; however, none did and at the beginning of the session, the facilitators checked that participants were happy to be recorded and no participants declined.

Fidelity assessment

Each audio recording was rated using a 12-item intervention fidelity checklist specifically designed for this study (Table S1). The 12 items were categorized into 4 overall themes:

1. Adherence to communication behaviours (items 1–5).
2. Management of the group (items 6–10).
3. Pacing of the intervention (item 11).
4. Participant responsiveness (item 12).

Each of the 12 items on the checklist was adapted from ones used in the fidelity assessment of previous health behaviour interventions (Song et al., 2010; Thompson et al., 2018) and rated using the Dreyfus Scale for assessing clinical competence ranging from 1 to 5, where '1' represented novice delivery, '2' advanced beginner, '3' adequate, '4' proficient and '5' expert (Dreyfus, 2004). Two assessors (TW and CT), who were independent of the NDPS delivery, separately rated all 30 recordings. To assist with rating the intervention sessions against the fidelity checklist items, the assessors were provided with the PowerPoint presentations and written session plans (not accessible by participants) used by the DPFs during delivery for each of the six 'core' education sessions. Initially, a sample of five recordings were analysed by the assessors independently, and the results were compared to clarify any disagreements between scores. Any disagreements were resolved through discussion with a third researcher who was part of the original intervention design team (CG). Following agreement, each assessor then independently scored the remaining 25 recordings, and these scores were used to calculate the inter-rater reliability between assessors.

Experience level

The level of experience for DPFs was defined by how many education sessions they had delivered at the time of the recording. The audio recordings were stratified a priori into two categories:

i. low-moderate experience was defined as delivering less than 20 sessions.
ii. advanced experience was defined as the facilitation of 21 or more sessions.

Statistical analysis

Descriptive statistics, including frequencies, percentages and standard deviations, were used to summarize the fidelity scores, for all 30 recordings. Inter-rater agreement was defined as the percentage of rater scores that were within one point. The initial 5 recordings were excluded from the inter-rater reliability

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assessment. Analysis of covariance (ANCOVA) was used to compare fidelity scores for low-moderate against advanced level of experience facilitators, while controlling for DPF. All statistical analysis was undertaken using SPSS version 26 (SPSS Inc) with a significance level set at .05.

Ethical considerations

Participants gave written informed consent to participate and agreed to have the sessions they attended audio recorded. Ethical approval was given by the Essex Research Ethics Committee (Ref: 10/H0301/55) and Norfolk and Norwich Hospitals NHS Foundation Trust Research and Development department (Ref: 2010EC11/CSP 56696).

RESULTS

Descriptive data

The characteristics of the sampled sessions are provided in Table 1. An even balance of sessions from intervention arms was reported. Due to limited availability of recordings, more than one sample was taken within the same year for DPF2, and two samples for Education session five were used for DPF 5. Median participant attendance was 4 per group.

Coder agreement

All 12 items in the checklist achieved at least 80% agreement between the two coders. Across all items, the mean inter-rater agreement was 86% (Table 2). According to the criteria of Landis (1977), this represents 'substantial agreement' (.61–.80) for four items and 'almost perfect agreement' (.81–1.0) for eight items (Landis & Koch, 1977). The mean score of the two coders was used in the subsequent analysis.

Diabetes prevention facilitator scores

The mean fidelity scores for each checklist item are presented in Table 2, and the mean scores for each DPF are shown in Table 3. A mean score of 3.47 (SD = .38) was achieved across all DPFs and all items, with item means ranging from 2.94 (SD = .68) for relapse management to 4.07 (SD = .54) for participant responsiveness. The intervention was delivered adequately or better in all four subcategories of intervention delivery. The facilitators achieved a mean score of ≥3.00 (adequate delivery or above) for 10 items

TABLE 1 Characteristics of education sessions selected for analysis.

	Education session					
	1	2	3	4	5	6
Diabetes prevention facilitator						
1	Yes	Yes	Yes	Yes	Yes	
2		Yes	Yes	Yes	Yes	Yes
3	Yes	Yes	Yes	Yes	Yes	
4	Yes	Yes		Yes	Yes	Yes
5	Yes	Yes	Yes		Yes ×2	
6	Yes	Yes	Yes		Yes	Yes

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TABLE 2 Inter-rater agreement and mean score per item across all DPFs.

	Percentage of scores within 1 point on the Likert scale (%; $n = 25$)	Mean (SD; $n = 30$)
1: Engaging the participant	80	3.92 (.59)
2: Exchanging information	84	3.23 (.62)
3: Explore importance	84	3.18 (.69)
4: Explore confidence	92	2.97 (.67)
5: Relapse management	80	2.94 (.68)
6: Leadership	92	3.81 (.73)
7: Sharing experiences	88	3.51 (.83)
8: Promote a climate of co-operation	80	3.62 (.63)
9: Valuing diversity	92	3.53 (.71)
10: Making the group attractive	96	3.73 (.77)
11: Comparison to session plan	80	3.11 (1.05)
12: Participant responsiveness	92	4.07 (.54)
Mean	86	3.47 (.38)

(83% of items). Only two item scores fell (marginally) below the adequate delivery standard of 3; exploring confidence ($M = 2.97$, $SD = .67$) and relapse management ($M = 2.94$, $SD = .68$).

Level of DPF experience

For sessions provided by facilitators with a low-to-moderate level of experience ($n = 12$), a mean score of 3.62 ($SD = .29$) was achieved across all checklist items. For sessions delivered by a facilitator with an advanced level of experience ($n = 18$ DPF), a mean score of 3.36 ($SD = .44$) was achieved across all items of the fidelity checklist. A non-significant effect was also found when analysing by item as opposed to across all items (Table 4). Although there was a tendency for fidelity to decrease over time (with facilitator experience) for 9 of the 12 items, the ANCOVA analysis showed no significant differences in any item of the fidelity questionnaire after controlling for DPF, $F_{(1,29)} = 2.32$, $p = .14$.

DISCUSSION

The Norfolk Diabetes Prevention Study intervention was delivered to an acceptable standard across all of the intended intervention components. However, there was scope for improvement in some of the techniques for some facilitators and overall score. In addition, there was a non-significant trend of decreasing intervention fidelity with DPF experience.

Possible explanations for the high levels of delivery fidelity (both between facilitators and over time) observed in the NDPS may include (a) the semi-structured nature of the intervention materials with clear session plans and facilitation materials for each session, (b) the DPF's own experience in delivering similar material previously (not measured), (c) the quality of the initial DPF training, and (d) the provision of refresher training including (generic rather than individual-specific) formative feedback, or (e) a combination of these potential explanations.

Relapse management (i.e. monitoring of progress over time and problem solving /reviewing of action plans to address any slips or lapses) was the intervention process that had the most sub-optimal scores, with four of the six DPFs not delivering this item to an acceptable standard (scoring <3). Problem solving is important in the development of long-lasting habits (Knäuper et al., 2020) and was part of the session plan for all the NDPS sessions. The lower fidelity for the delivery of relapse management

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TABLE 3 Mean, maximum and minimum score by facilitator and item.

	DPF 1			DPF 2			DPF 3			DPF 4			DPF 5			DPF 6		
	M (*SD*)	Mi	Ma	*M* (*SD*)	Mi	Ma	*M* (*SD*)	Mi	Ma	*M* (*SD*)	Mi	Ma	*M* (*SD*)	Mi	Ma	*M* (*SD*)	Mi	Ma
Engagement	3.7 (.5)	3.0	4.3	4.8 (.4)	4.3	5.0	4.0 (.7)	3.0	4.8	3.8 (.3)	3.3	4.0	3.8 (.4)	3.5	4.5	3.6 (.5)	3.0	4.0
Exchanging Information	3.4 (.5)	3.0	4.0	3.9 (.3)	3.5	4.3	2.9 (.9)	1.5	3.5	3.1 (.5)	2.5	3.8	3.2 (.4)	2.5	3.5	3.1 (.6)	2.5	4.0
Exploring Importance	2.7 (.4)	2.0	3.0	3.8 (.6)	3.0	4.5	3.0 (1.0)	1.5	4.0	3.1 (.6)	2.3	3.8	3.7 (.6)	3.0	4.5	2.9 (.2)	2.5	3.0
Exploring Confidence	2.7 (.7)	2.0	3.5	3.7 (.5)	3.0	4.3	2.7 (.9)	1.5	4.0	3.1 (.5)	2.5	3.8	3.1 (.7)	2.5	4.0	2.7 (.5)	2.3	3.3
Relapse Management	2.9 (.9)	2.0	4.3	3.7 (.8)	2.5	4.5	2.9 (.7)	1.8	3.5	2.5 (.3)	2.0	2.8	3.0 (.5)	2.5	3.8	2.8 (.3)	2.5	3.3
Leadership	4.1 (.6)	3.5	5.0	4.9 (.1)	4.8	5.0	3.5 (.8)	2.3	4.3	3.4 (.3)	3.0	3.8	3.6 (.4)	3.3	4.3	3.4 (.6)	2.5	4.0
Sharing Experiences	4.3 (.4)	4.0	5.0	4.1 (.7)	3.3	5.0	3.9 (.4)	3.5	4.5	2.8 (1.0)	1.5	3.8	2.9 (.6)	2.3	3.5	3.2 (.5)	2.5	3.8
Climate of Cooperation	4.1 (.6)	3.5	5.0	4.3 (.5)	3.5	4.8	3.5 (.5)	3.0	4.3	3.5 (.5)	3.0	4.0	3.1 (.4)	2.5	3.5	3.3 (.6)	2.5	4.0
Valuing Diversity	4.1 (.7)	3.3	5.0	4.1 (.4)	3.5	4.5	3.3 (.9)	2.0	4.5	3.5 (.6)	2.5	4.0	3.0 (.5)	2.5	3.5	3.3 (.5)	2.8	4.0
Making the Group Attractive	4.2 (.6)	3.5	5.0	4.7 (.3)	4.5	5.0	3.4 (.8)	2.0	4.3	3.6 (.5)	2.8	4.0	3.0 (.7)	2.5	4.0	3.7 (.3)	3.5	4.3
Comparison to Session Plan	2.8 (1.0)	1.8	4.0	4.2 (.4)	3.5	4.5	3.0 (1.1)	1.0	3.8	2.2 (.5)	1.8	3.0	3.5 (1.1)	2.0	4.8	3.1 (1.1)	1.5	4.3
Participant Responsiveness	4.6 (.4)	4.0	5.0	4.5 (.4)	4.0	5.0	4.0 (.7)	3.0	4.5	3.8 (.4)	3.3	4.3	3.5 (.3)	3.3	3.8	4.1 (.3)	3.8	4.5

Abbreviations: DPF, Diabetes Prevention Facilitator; *M*, Mean; Ma, Maximum; Mi, Minimum; *SD*, Standard Deviation.

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TABLE 4 Mean score for low moderate compared to advance level of experience.

	Low-moderate level of experience ± 95% CI (n = 12)	Advance level of experience ± 95% CI (n = 18)	ANCOVA p-value
1: Engaging the participant	4.12 ± .33	3.78 ± .28	.127
2: Exchanging information	3.32 ± .36	3.18 ± .29	.530
3: Explore the importance	3.48 ± .39	2.98 ± .32	.057
4: Explore confidence	3.23 ± .39	2.79 ± .32	.94
5: Relapse management	3.23 ± .39	2.75 ± .31	.057
6: Leadership	4.00 ± .37	3.68 ± .31	.201
7: Sharing experiences	3.68 ± .40	3.39 ± .33	.268
8: Promote a climate of co-operation	3.57 ± .30	3.65 ± .25	.695
9: Valuing diversity	3.58 ± .39	3.5 ± .32	.741
10: Making the group attractive	3.66 ± .42	3.78 ± .35	.640
11: Comparison to session plan	3.54 ± .61	2.82 ± .49	.070
12: Participant responsiveness	4.01 ± .29	4.11 ± .23	.604
Total	3.66 ± .54	3.34 ± .43	.139

may reflect pushback from the participants, who may have tired of going through the same process at the start of every session.

One further possibility is that DPF develop a more personal relationship with, and knowledge of, participants, through which they made judgement to tailor the intervention content accordingly, although this was not explicitly specified in the intervention protocol. This is an acknowledged effective clinical method (Royal College of General Practitioners, n.d.), and such group interventions in the future could train for, evaluate and accept some modification of advice to make each group intervention maximally effective. However, this is speculative and further research (such as interviewing of the NDPS facilitators) is needed to understand the reasons for the under-delivery of this intervention process.

Analysis of intervention fidelity conducted on the NHS Diabetes Prevention Programme showed only seven (37%) of 19 specified behaviour change techniques (BCTs) were delivered, including 'substantial under-delivery of BCTs that were designed to improve self-regulation of behaviour, for example, those involving problem solving and self-monitoring of behaviour' (French et al., 2021). Why this difference exists is unclear. In contrast, studies examining a telephone delivered Health Coaching intervention (Timm et al., 2021) and an intervention designed to increase professional engagement in prevention programmes (Sánchez et al., 2021) showed similarly high levels of fidelity to those reported here. Our findings contrast with other data from health behaviour or self-care interventions which indicate that delivery quality often varies considerably between facilitators (Cross et al., 2022; Frost et al., 2019).

Strengths, limitations and further research needed

This is the first study, to our knowledge to examine both intervention fidelity and changes in fidelity over time for a behaviour change intervention. The assessment of intervention fidelity adds further explanatory data to the already published Norfolk Diabetes Prevention Study trial (Sampson et al., 2021), which helps to explain the effectiveness of the intervention (Lambert et al., 2017) and could help to inform future improvements in intervention delivery. The use of session recordings allowed direct observation of the intervention that was delivered and fidelity was rated by multiple coders, neither of whom were involved in the development or delivery of the intervention.

However, there are some limitations that need to be acknowledged: The current analysis provides data from a selected sample of just 30 of the core intervention sessions delivered in the NDPS and may not be representative of the sessions as a whole. Although fidelity of the maintenance sessions is unclear

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as they were not included in this analysis. As behaviour change and maintenance are distinctly different, it would make the interpretation of the results more challenging if they were included in this analysis (Kwasnicka et al., 2016). Although a fidelity assessment of the maintenance sessions would be a worthwhile analysis to undertake. In addition, knowledge that they were being recorded may in some way have affected performance.

Even though the NDPS was a highly pragmatic study, the transferability of these findings to wider implementations of this programme is not clear. Hence, delivery fidelity should be periodically assessed and steps taken to enhance it (through high-quality training and training updates) during the early phases of implementation. Applying the checklist to a larger sample might improve the generalisability of the estimates of fidelity and also of any changes in fidelity over time. It may also (with purposive sampling) allow for a within-subject, rather than the current between-subject analysis which could reduce the noise in the data. A larger sample would also allow for analysis of associations between aspects of delivery quality and changes in participant outcomes, such as weight loss and changes in blood glucose. Although fidelity was rated by multiple coders, the scoring is, by its nature, subjective and so a different team may have generated different results. However, the fidelity assessment was designed using a number of recognized methodologies (Walton et al., 2020). Finally, video recording would have allowed for the assessment of non-verbal communication, facilitator's body language, and attentiveness of the participants. However, audio-recording provided a less intrusive and more easily anonymised method for assessing delivery fidelity hence why it was used for this study. Despite these limitations, this study shows that it is possible to undertake a purposeful fidelity assessment which can be used to further develop the intervention.

CONCLUSION

The Norfolk Diabetes Prevention Study intervention was delivered to an acceptable standard, with consistency between facilitators for most intervention processes with no evidence of a decline in fidelity over time. The consistency of delivery may reflect the rigorous and well-structured intervention design and training methods used, and this could in turn help to explain the high degree of effectiveness of this large-scale, real-world diabetes prevention trial. Although this study shows that it is possible to deliver a behaviour change trial with acceptable fidelity.

AUTHOR CONTRIBUTIONS

NG, JK, LP, SA, JS, AH, MP, JS and CG were involved in the delivery and analysis of the Norfolk Diabetes Prevention Study which was led by MS. CG designed the fidelity study with the help of the other authors. TW and CT undertook data analysis with the support of NG and CG. TW wrote the initial draft with the support of CT. All authors contributed to and approved the final manuscript.

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No funding was received for this study.

CONFLICT OF INTEREST STATEMENT

The authors have no competing interests to declare.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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CONSENT FOR PUBLICATION

Not applicable.

ETHICAL APPROVAL AND INFORMED CONSENT TO PARTICIPATE

This study received ethical approval from the NRES Committee East of England Essex (REC number: 10/H0301/55) on 3 January 2011. The informed consent from all participants was obtained. The authors confirm that all methods were carried out in accordance with the relevant guidelines.

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