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## Using mixed methods to assess treatment fidelity and its influencing factors in a complex self-management intervention

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**Title**

Using mixed methods to assess treatment fidelity and its influencing factors in a complex self-management intervention

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**ABSTRACT:**

**Objectives and design:** Despite an increasing awareness of the importance of addressing treatment fidelity within complex behaviour change interventions, fidelity is often poorly assessed in such interventions with few examples of a comprehensive investigation of fidelity and its influencing factors. This mixed methods study aimed to establish the fidelity of a complex self-management intervention and explore the reasons for these findings using a concurrent/triangulation design.

**Setting:** Feasibility trial of the SOLAS self-management intervention for people with osteoarthritis and back pain, delivered in primary care physiotherapy

**Methods and outcomes:** 60 SOLAS intervention sessions were delivered across seven sites by nine physiotherapists. Fidelity of delivery was evaluated using 1) audio-recordings (n=60), direct-observations (n=24) and self-report checklists (n=60) and 2) individual semi-structured interviews with all physiotherapists (n=9). Quantitatively, fidelity was calculated using percentage means and standard deviations. Qualitative data were analysed using thematic analysis. Integration of quantitative and qualitative data occurred at an interpretation level using triangulation.

**Results:** Quantitatively, fidelity scores were high for all assessment methods; with self-report (92.7%) consistently higher than direct-observations (82.7%), or audio-recordings (81.7%). There was significant variation between physiotherapists' individual fidelity scores (69.8% - 100%). Both qualitative and quantitative data found that physiotherapists' knowledge and previous experience were factors that influenced their fidelity. The qualitative data also postulated participant-level and programme-level factors as additional elements that influenced fidelity.

**Conclusion:** This study contributes to the limited evidence regarding the use of fidelity assessment methods within the area of complex behaviour change interventions. The findings suggest a combination of quantitative methods is suitable for the assessment of fidelity within this context, depending on resources available. A mixed methods approach, integrating both quantitative and qualitative data, provided a more insightful understanding of fidelity and its

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3 influencing factors, offsetting weaknesses inherent in using each research method in  
4 isolation.  
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### 8 **Article summary – strengths and limitations**

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10 • This comprehensive investigation of fidelity and its influencing factors provides valuable  
11 information on fidelity assessment methods and factors to be considered in developing  
12 and evaluating complex behaviour change interventions
- 13  
14 • The novel use of mixed methods to assess fidelity in this study enabled increased  
15 certainty in findings where qualitative data corroborated the quantitative results
- 16  
17 • This study does not explore the fidelity of the *quality* of delivery (e.g. therapist  
18 competence) which will be reported elsewhere  
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# USING MIXED METHODS TO ASSESS TREATMENT FIDELITY AND ITS INFLUENCING FACTORS IN A COMPLEX SELF-MANAGEMENT INTERVENTION

## INTRODUCTION

Treatment fidelity is an important, yet often overlooked aspect of behaviour change interventions and has been defined as the degree to which an intervention, treatment or program is implemented as intended by the intervention developers.<sup>1,2</sup> Without adequately addressing fidelity in behaviour change research, it is uncertain that changes observed in study outcomes are due to the influence of the independent variable (the intervention being investigated) and not due to variability in its implementation, e.g. extraneous elements that may have been added (either accidentally or purposely), or essential elements of the intervention that were omitted.<sup>3</sup> In particular, as behaviour change interventions are often complex interventions that typically involve several components with the potential to affect or influence outcomes separately, it is especially important to incorporate adequate fidelity planning and assessment into the development of interventions of this nature.<sup>4</sup>

Despite a recent increased emphasis on improved assessment and reporting of what happens within complex behaviour change interventions,<sup>5,6</sup> fidelity is still poorly addressed within this context, with few examples of fidelity being addressed comprehensively or reported adequately.<sup>7-9</sup> Where studies have assessed fidelity within a behaviour change healthcare context, there is often limited exploration of the factors that might have influenced that fidelity.<sup>10,11</sup> Although the use of both quantitative and qualitative methods has been previously recommended to comprehensively assess fidelity,<sup>12-14</sup> this guidance is not consistently followed. Consequently, the use of quantitative methods in isolation may not allow for exploration of the factors influencing fidelity, knowledge of which could improve how fidelity is enhanced and assessed in future similar interventions.<sup>15</sup> For example, French et al.<sup>11</sup> used audio-recordings and self-report methods to assess the fidelity of delivery of an educational intervention for general practitioners. The authors acknowledged that the quantitative study design did not allow them to explore the reasons for variations in fidelity scores found.

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3 According to existing guidelines for addressing fidelity within behaviour change research  
4 developed by the National Institutes of Health Behaviour Change Consortium (NIHBCC),<sup>14</sup>  
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According to existing guidelines for addressing fidelity within behaviour change research developed by the National Institutes of Health Behaviour Change Consortium (NIHBCC),<sup>14</sup><sup>16</sup> the fidelity of delivery of the intervention by providers (or Treatment Delivery) is one particularly important aspect of fidelity. Treatment delivery considers strategies that enhance the fidelity of delivery (e.g. using treatment manuals or intervention protocols) and methods that assess this delivery (e.g. provider self-report, audio or video-recorded observations and direct *in vivo* observations). However, although previous research has advocated a combination of these strategies in order to comprehensively assess fidelity,<sup>17,18</sup> limited examples exist within the literature. Additionally, few studies have explored the relationship between these methods, and the accuracy of potentially more feasible methods against the ‘gold standard’ of direct observations using pre-specified criteria<sup>19</sup> has been poorly investigated.<sup>14,15,20</sup> As a result, there is little evidence to justify the selection of one method over another, or to inform the use of multiple methods simultaneously.

The current study is set within the context of the SOLAS (Self-Management of Osteoarthritis and Low back pain through Activities and Skills) feasibility trial [ISRCTN49875385].<sup>21</sup> The trial aims to test the feasibility of an intervention to promote self-management for people with osteoarthritis (OA) of the hip/knee and/or chronic low back pain (CLBP). The intervention consists of six weekly sessions of 90 minutes to be delivered by a primary care physiotherapist to a group of six to eight people. Each session is divided into education and exercise categories (each approximately 45 minutes in duration), with subcomponents as detailed in Table 1. Prior to participation, physiotherapists underwent a two-day training course where background variables were collected, in addition to a post-training assessment.<sup>22</sup> Details of the development and testing of the fidelity protocol used in this study are described elsewhere.<sup>23</sup>

The aim of this study was to explore and evaluate the fidelity of treatment delivery within the context of a complex behaviour change intervention using a mixed methods approach.

Specifically, the study objectives were:

- 1) To evaluate the agreement of multiple methods for assessing fidelity of treatment delivery
- 2) To establish the fidelity of treatment delivery of the SOLAS complex behaviour change intervention
- 3) To explore the potential factors that may have influenced these fidelity results

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<b>Session Number</b>	1	2	3	4	5	6
Self-management behaviours/ skills targeted	<ul style="list-style-type: none"> <li>Physical activity</li> <li>Goal-setting</li> </ul>	<ul style="list-style-type: none"> <li>Pacing (balancing activity/rest)</li> <li>Physical activity</li> <li>Goal-setting</li> </ul>	<ul style="list-style-type: none"> <li>Balanced weight/ healthy diet</li> <li>Physical activity</li> <li>Goal-setting</li> </ul>	<ul style="list-style-type: none"> <li>Managing pain with pain relief</li> <li>Physical activity</li> <li>Goal-setting</li> </ul>	<ul style="list-style-type: none"> <li>Managing mood (with relaxation)</li> <li>Physical activity</li> <li>Goal-setting</li> </ul>	<ul style="list-style-type: none"> <li>Long-term management</li> <li>Physical activity</li> <li>Goal-setting</li> </ul>
<b>Session Structure</b>						
<b>Category</b>	<b>Category Subcomponents</b>	<b>Aim/content</b>				<b>Intended Duration</b>
Education	Materials	Participants are provided with materials intended to supplement and enhance their understanding and uptake of skills, such as pedometers, participant activity diaries, participant handbook and relaxation CDs				45 minutes
	Introduction and Review	At the start of each session the physiotherapist reviews goals and action plans with participants and problem-solving where necessary				
	Education	Physiotherapist facilitates a group discussion on the targeted self-management skill/behaviour of the session using Powerpoint slides and projector to provide information				

	Review and Planning	Before the session concludes, the physiotherapist briefly recaps participants' planned activity levels and action plans for the week ahead									
Exercise	Exercise	Participants are provided with an opportunity to attempt and practice a variety of exercises									45 minutes
<b>Samples involved</b>											
	<b>Wave 1</b>				<b>Wave 2</b>						<b>Total n=</b>
Physiotherapy Site code	A	B	C	D	A	B	C	E	F	G	<b>10 (7)*</b>
Physiotherapist code	A1	B1	C1	D1	A1	B2	C2	E1	F1	G1	<b>9**</b>
Number of participants recruited	4	6	4	2	4	4	5	4	7	5	<b>45</b>
Sessions delivered	6	6	6	6	6	6	6	6	6	6	<b>60</b>
Direct Observations	3	3	3	3	2	2	3	2	1	2	<b>24 (40%)</b>
Self-Report	6	6	6	6	6	6	6	6	6	6	<b>60 (100%)</b>
Audio-Recordings (rater 1)	6	6	6	6	6	6	6	6	6	6	<b>60 (100%)</b>
Audio-Recordings (rater 2)	3	3	3	3	0	0	0	0	0	0	<b>12 (20%)</b>
**Seven sites were involved in total, but three of these delivered the intervention in both waves											
*One physiotherapist delivered the intervention in both waves											



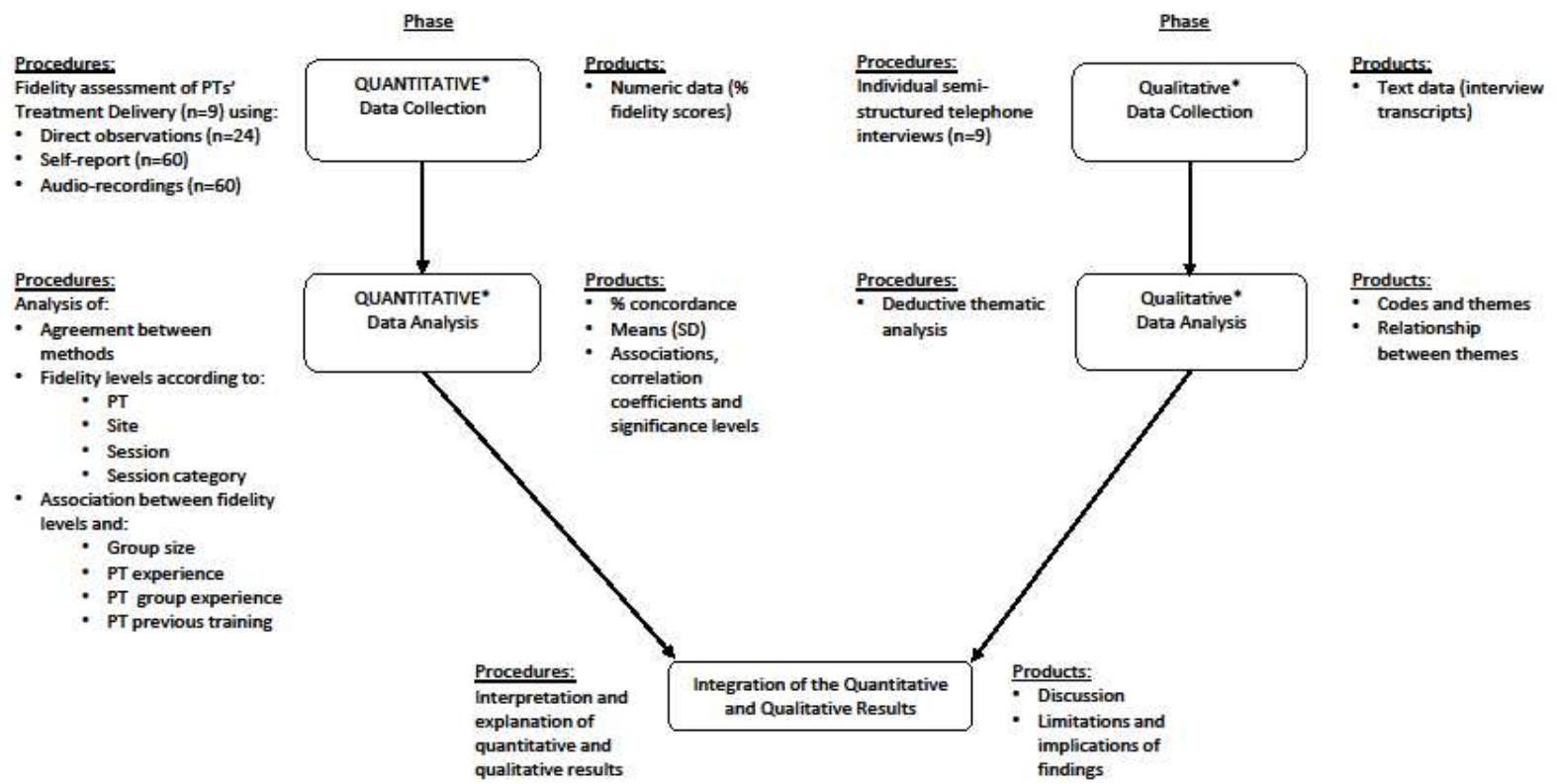
## METHODS

### Ethics

Ethical approval for this study was granted by University College Dublin's Human Research Ethics Committee (LS-13-54). Written informed consent was obtained from all physiotherapists and participants prior to any observations or interviews.

### Design

This observational study was a convergent/triangulation mixed methods design.<sup>24</sup> This mixed methods approach was chosen as it was felt that thorough integration of findings from both quantitative and qualitative methods would achieve a more comprehensive answer to the study questions by enabling the methods to be 'greater than just the sum of their parts'.<sup>25</sup> Figure 1 graphically illustrates the study design, outlining the sequence of research activities, the priority of the methods and the stage at which integration occurred.<sup>26</sup>



\*capitalisation represents weighting or priority, PT = physiotherapist, SD = standard deviation

Figure 1: Diagrammatic representation of mixed methods convergent/triangulation design

## Quantitative phase

### Study sample and procedure:

Data were collected during two waves of the SOLAS feasibility trial (Table 1), representing 71% of the overall trial data. Following pilot testing, it was decided to conduct 24 (40% of sessions) randomly selected direct observations (rated by ET), 60 (100%) self-report (rated by the physiotherapists) and 60 (100%) audio-recordings (rated by ET) to assess fidelity of treatment delivery using a-priori checklists that had been previously found to be feasible for use.<sup>23</sup> To assess inter-rater reliability, 12 sessions (20%) were rated by a second independent rater (AK).<sup>10</sup> Checklists were structured into the SOLAS categories as detailed in Table 1 with components chosen based on the intended content. Session duration (dose) was documented by all methods, and attendance was recorded by self-report.

### Data analysis:

Fidelity data analysis was consistent with standard procedures<sup>15,27,28</sup> using SPSS v20. Specifically, levels of agreement between methods and inter-rater reliability of audio-recorded data were assessed using percentage concordance. Overall mean fidelity levels and fidelity levels according to physiotherapy site, physiotherapist, session and session category were obtained by calculating total scores as a percentage of the total possible score. Means data were compared using ANOVAs and Kruskal-Wallis tests. Fidelity of dose was established by calculating the difference between the actual and the intended session duration using a one-sample Wilcoxon test. Levels of fidelity were interpreted as previously reported in the literature, with 80-100% adherence interpreted as 'high' fidelity, 51-79% as 'moderate' and 0-50% as 'low' fidelity.<sup>3,29,30</sup> Finally, the relationship between fidelity levels and 1) the number of participants present (group size) and 2) physiotherapist variables, i.e. experience (years qualified), group experience (years delivering group physiotherapy), knowledge of intervention (post-training evaluation score) and previous relevant training (Supplementary File 1), were calculated using Spearman's correlation coefficient and Mann-Whitney U test. These physiotherapist variables were chosen as previous research in other contexts has found that provider-level variables (e.g. experience) may influence fidelity of intervention delivery.<sup>17,31-35</sup>

## Qualitative phase

The aim of the qualitative phase was to explore physiotherapists' opinions of fidelity of intervention delivery and the factors that they felt may have influenced their fidelity.

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3 Individual semi-structured telephone interviews were conducted by an experienced  
4 qualitative researcher (SG) with each physiotherapist (n=9) within two weeks of intervention  
5 delivery completion. Interviews were audio-recorded and transcribed verbatim. Deductive  
6 thematic analysis was used to analyse the interviews as it is a flexible method that works with  
7 a range of research questions, including understanding people's experiences of programmes  
8 and health-care interventions.<sup>36</sup>

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15 Meaningful units of text were highlighted within each interview, then summarised and coded.  
16 Codes dealing with similar issues were grouped across all interviews and refined into themes.  
17 The reliability of themes was established by a second reviewer (AK) who independently  
18 analysed a randomly selected sample of 50% of the transcript extracts using the coding  
19 framework. Percentage agreement was determined between the reviewers' respective coding  
20 of extracts. If agreement was less than 70%, consensus on conflicting decisions was obtained  
21 through discussion.<sup>37</sup>

## 22 23 24 25 26 27 28 **Integration**

29 Integration of quantitative and qualitative data occurred at an interpretation level using  
30 triangulation methodology. Specifically, a meta-matrix was created to facilitate comparison  
31 of the findings (Table 5).<sup>38</sup> This involved presenting the quantitative data in a tabular format  
32 alongside summarised qualitative themes, which enabled a transparent approach to  
33 determining convergence, discrepancy or silence across the findings of the data sets.<sup>39</sup>  
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Convergence was defined as general agreement between the data sets on the element of  
comparison (e.g. overall quantitative fidelity score compared to the majority of  
physiotherapist opinions of their fidelity levels), while discrepancy was defined as general  
disagreement between the data sets on the element of comparison.<sup>39</sup> Silence was defined as  
where one set of results addressed a theme or example, but the other set of  
results did not yield any relevant data.<sup>39</sup>

## 51 52 **RESULTS**

### 53 54 55 **Quantitative findings**

56 Agreement:

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3 Agreement between direct observations and self-report was 74.6%, 75.4% between self-  
4 report and audio-recordings (rater 1) and 86.6% between direct observations and audio-  
5 recordings (rater 1). Inter-rater reliability of audio-recordings (rater 1 vs rater 2) was 81.3%.  
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8 Further detail is provided in Supplementary File 2.  
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#### 11 Fidelity of content:

12 Fidelity was found to be high in all assessment methods, ranging from 81.7% (Audio-  
13 recordings) to 92.7% (Self-report). Table 2 details the fidelity results for each method with  
14 scores below 80 (cut-off for 'high' fidelity) shaded. Significant differences were found  
15 between Physiotherapist scores and between Category scores.  
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	<b>Direct Observations (DO)</b>	<b>Self-Report (SR)</b>	<b>Audio 1 (AO)</b>
	<b>% (SD)</b>	<b>% (SD)</b>	<b>% (SD)</b>
<b>Total % mean fidelity score (SD)</b>	82.7% (10)	92.7% (6.4)	81.7% (12)
<b>% mean fidelity score per session (SD)***</b>			
1	88.8% (5.24)	95% (4.5)	91.6% (4.5)
2	82.8% (5.7)	92% (6.9)	86.8% (10.5)
3	85.6% (12.9)	96% (4.2)	81.4% (10.6)
4	83.3% (14.4)	90.9% (8.3)	75% (14)
5	74.1% (11.9)	89.4% (8.1)	78.7% (11)
6	82% (9.6)	92.7% (3.78)	74.9% (12)
<b>% mean fidelity score per site (SD)***</b>			
A (delivered twice, same physiotherapist)	78.7% (7.6)	95% (5.4)	81.3% (11.5)
B (delivered twice, two physiotherapists)	76.7% (5.6)	92.8% (5.3)	71.1% (10)
C (delivered twice, two physiotherapists)	84.8% (11.8)	91.8% (7.7)	84.9% (8.1)
D	87.2% (4)	93.2% (2.9)	87.1% (4.4)
E	83.1% (13)	94.3% (3.8)	88.3% (8.7)

F	72.5%	85.2% (9.6)	72.9% (15)
G	100% (0)	94.7% (4.4)	92.8% (5.4)
<b>% mean fidelity score per category (SD)*</b>			
Materials	72.1% (19.4)	86% (17)	61.1% (29.6)
Introduction and Review	82.6% (16.3)	92.9% (12.8)	76.2% (24.5)
Education	93.3% (8.6)	97.1% (6.6)	95.4% (6.9)
Exercise	80.4% (14)	95.4% (7.1)	82.4% (13)
Review and Planning	77.1% (33)	90.8% (21.6)	69.8% (39.6)
<b>% mean fidelity score per physio (SD)**</b>			
A1	78.8% (7.6)	95.1% (5.4)	81.3% (11.5)
B1	76.1% (7.9)	92.2% (7.2)	72.3% (9.3)
B2	77.5% (0.4)	93.4% (3)	72.6% (12.5)
C1	93.4% (2)	85.2% (4.6)	91% (3.5)
C2	76.2% (11)	98.5% (1.9)	78.8% (6.6)
D1	87.2% (4)	93.2% (2.9)	87.1% (4.4)
E1	83.1% (13)	94.3% (3.8)	88.3% (8.7)
F1	72.5%	85.2% (9.6)	69.8% (14.7)
G1	100% (0)	94.7% (4.4)	95.8% (5.4)
*Significant differences between Categories according to DO (p=0.007), SR (p<0.001) and AO (p<0.001)			
** Significant differences between Physiotherapists according to DO (p=0.019), SR (p=0.004) and AO (p<0.001)			
***Significant differences between Sites (p<0.001) and between Sessions (p=0.007) according to AO, not significantly different			

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according to DO and SR.  
Shaded areas = scores < 80%

For peer review only



Fidelity of dose (duration of sessions):

All methods found a statistically significant difference between the actual duration of the exercise component and its intended duration of 45 minutes. When the dosage was analysed for each individual session for all methods combined, a statistically significant difference ( $p < 0.001$ ) was only found for Session 1 between the actual and intended duration. The difference between the actual and intended dosage for all other sessions was not found to be statistically significant.

Group size – participants in attendance:

The average numbers of participants present for all groups across all sessions was 3, with an SD of 1.3. Overall, group attendance ranged from one to six participants for any session throughout both waves. The total number of participants recruited for each group was significantly different between physiotherapists (e.g. seven participants were recruited for the group delivered by physiotherapist F1 compared to only two recruited for the group delivered by D1), as were the numbers of participants present (average group size). The size of groups did not differ significantly between sessions.

Factors associated with fidelity:

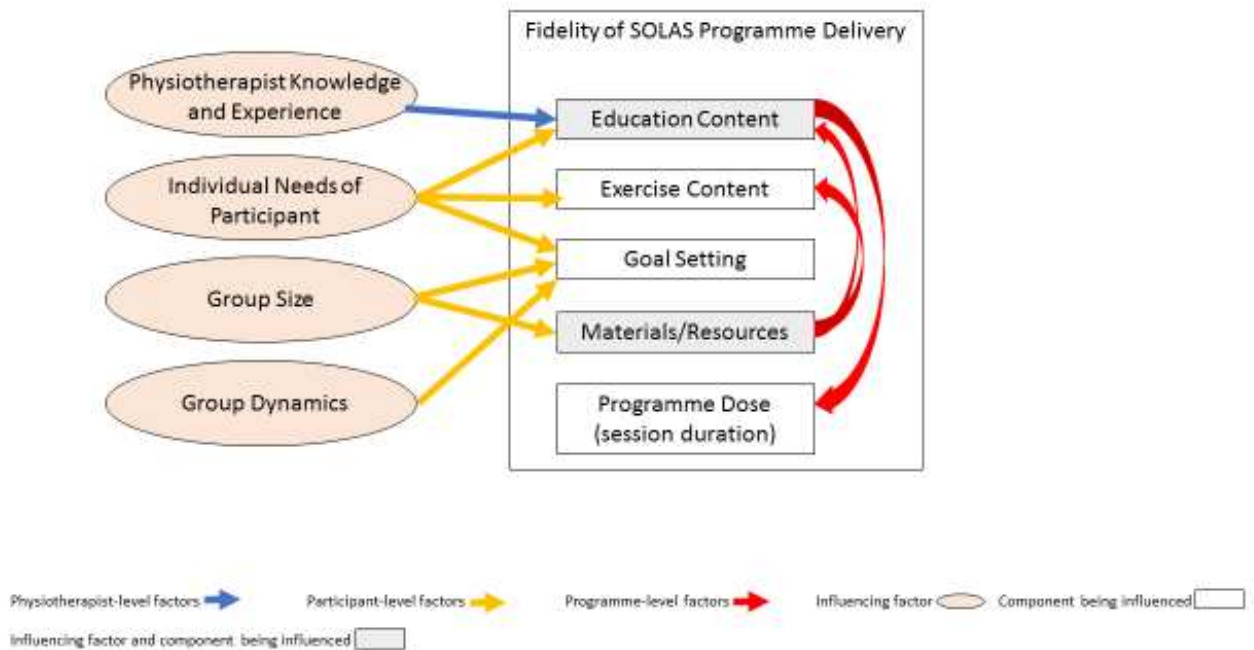
Both direct observation and audio-recorded data showed a significant correlation between fidelity scores and the physiotherapists' post-training evaluation scores. Direct observation data also found a significant negative correlation between group sizes and the fidelity scores. Physiotherapist years qualified and experience of delivering groups were found to have significant, negative correlations with fidelity scores for the audio-recorded and self-report data respectively (Table 3).

Variable	Direct Observations	Self-Report	Audio-Recordings	Statistical Test
Group size (number present)	-0.434 ( $p=0.034$ )*	-0.215 ( $p=0.98$ )	-0.193 ( $p=0.151$ )	Spearman's $r$ ( $p$ -value)
Physiotherapist experience (years qualified)	-0.09 ( $p=0.676$ )	-0.186 ( $p=0.154$ )	-0.346 ( $p=0.008$ )*	

Physiotherapist group experience (years delivering group physiotherapy)	0.171 (p=0.424)	-0.364 (p=0.004)**	0.136 (p=0.312)	
Physiotherapist Post-Training Evaluation Score (%)	0.581 (p=0.003)**	-0.152 (p=0.245)	0.314 (p=0.018)*	
Physiotherapist previous relevant training (yes/no)	$U=33$ (p=0.302)	$U=201$ (p=0.107)	$U = 243$ (p=0.840)	Mann-Whitney U (p-value)
*p is significant at $p<0.05$ , ** $p<0.005$				

### Qualitative findings

Inter-rater reliability of coding achieved 81.6% agreement. Overall, physiotherapists felt that they had delivered the programme with good fidelity. All physiotherapists discussed some deviations from the protocol or adaptations made during delivery, i.e. goal-setting was found to be challenging to complete as intended. Other adaptations either concerned difficulties with use of programme materials (e.g. using the projector) as intended or providing additional information during the education content. Five physiotherapists also discussed deviation from protocol in relation to duration, mostly during the first session, with one stating that her *'time management around the education wasn't always exactly what it should have been'* (B1, transcript line 278-286). In terms of factors that influenced fidelity (i.e. reasons discussed for the aforementioned adaptations and deviations), six themes were found that were structured into three levels of factors – physiotherapist, participant and programme-level (Figure 2).



**Figure 2:** Visual representation of themes of qualitative interviews – factors influencing fidelity of SOLAS delivery

At the physiotherapist level, eight of the nine physiotherapists felt that knowledge of the content of the SOLAS programme facilitated their delivery of the education session and made it easier. Conversely, deviations from protocol within the education content discussed by six physiotherapists were due to the provision of additional information which was influenced by their previous experiences of delivering similar groups (e.g. talking more about pain pathophysiology because of previous classes delivered on this topic). This formed the theme '*Physiotherapist knowledge and experience influenced delivery of SOLAS - education content*'.

At the participant level, five physiotherapists felt that participants' individual needs such as their understanding of content or language literacy levels influenced the delivery of education and exercise components and that adaptation sometimes occurred in response to these needs, creating the theme of '*Individual needs influenced delivery of SOLAS - education, exercise, goal-setting*'. The number of participants present was discussed by seven physiotherapists as another participant-level factor that influenced fidelity of delivery and formed the participant-

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3 level theme of '*Group size influenced delivery of SOLAS - goal-setting, use of materials*'. A  
4 further participant-level theme was '*Group dynamics influenced delivery of SOLAS - goal-*  
5 *setting*' as four physiotherapists felt that groups with good dynamics and interaction between  
6 participants led to better group discussions and better facilitation of goal setting.  
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11 The '*Amount of education content influenced delivery of SOLAS – dosage*' was a programme-  
12 level factor discussed by six physiotherapists, who felt that the amount of education content  
13 that was involved in the first session led to more time spent on the education aspect than  
14 intended as per protocol. Finally, all nine physiotherapists believed that the good resources  
15 (e.g. Powerpoint slides, venue) enhanced and facilitated the delivery of the programme as  
16 intended and that occasionally poor or problematic resources negatively influenced the  
17 delivery of the programme as intended. This created the theme '*Resources/materials*  
18 *influenced delivery of SOLAS – education and exercise content*'. Exemplary quotes are  
19 provided in Table 4.  
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<b>Factor level</b>	<b>Theme</b>	<b>Exemplary quote (Physiotherapist code, transcript line)</b>
<b>Physiotherapist</b>	Physiotherapist knowledge and experience influenced delivery of SOLAS - education content	<i>'In my previous experience I would have done a lot more actually on the pain side of things...so in my previous class I would have had, you know, maybe one full class on maybe pain perception and, kind of, the influence of emotion and feelings...so I think I would have probably maybe talked a lot more around that pain section than maybe somebody else would have'. (C1, 75-99)</i>
<b>Participant</b>	Individual needs influenced delivery of SOLAS - education, exercise, goal-setting	<i>'People don't like writing them [action plans] there and then you know with pencils given and whatever - yes it's very hard to get people to write down things like that....Where I work there is a lot of people health literacy is very low...so therefore that's a challenge for them...so I tend to be very careful about pushing it out really' (F1, 141-187).</i>
<b>Participant</b>	Group size influenced delivery of SOLAS – goal-setting, use of materials	<i>'The only thing I might find a little bit hard would be the goal setting. I suppose you'd - that would be a bit more challenging because you'd have more numbers in the group' (G1, 118-132)</i>
<b>Participant</b>	Group dynamics influenced delivery of SOLAS - goal-setting	<i>'People were willing to engage you know as a group, in their goals.....so that made it very easy that we didn't actually have any clients that weren't willing to talk in the group, so it was very much an interactive group' (E1, 225-231).</i>
<b>Programme</b>	Amount of education content influenced delivery of SOLAS – dosage (session duration)	<i>'I found the content in week one was nearly too much... by the time I finished talking and ran through the exercises, the hour and a half was finished. And so nobody actually practiced any of the exercises on the first day' (B2, 96-106).</i>

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<b>Programme</b>	Resources/materials influenced delivery of SOLAS – education and exercise content	<p><i>'The slides didn't work for me this time.... You can't lock that room.... once or twice I didn't bring the laptop at all and I just had to print it out, all of the slides on A4 laminate and so we talked all the slides....' (F1, 207-240)</i></p> <p><i>'I think I only left out maybe three [exercise] stations, something like that. Because we didn't have a bouncer and...we didn't have a bed' (C1, 113-121).</i></p>
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### Integrating qualitative and quantitative findings

Each theme was further analysed according to the quantitative data comparing physiotherapists who scored 'high' (i.e.  $\geq 80\%$ ; physiotherapists D1, C1, E1 and G1) to those who scored 'moderate' (i.e.  $\geq 50-79\%$ ; B1, B2, C2 and F1). Physiotherapist A1 was not included in this analysis as her score was categorised as 'moderate' by direct observations and 'high' by audio-recorded data at 78.7% and 81.3% respectively. A difference between these physiotherapist groups was found in only one theme, '*Group size influenced delivery of SOLAS*'. Physiotherapists who scored higher on the fidelity assessments (average group size of 2.5 participants), believed it was easier to deliver goal-setting as intended with smaller groups. Conversely, physiotherapists with moderate fidelity scores (average group size of 3.7 participants) felt it was harder to facilitate goal-setting as intended with less numbers and believed it would be easier with bigger groups due to better engagement and group discussion. Further details of the triangulation are provided in Table 5.

<b>Table 5: Triangulation of quantitative and qualitative results – convergence and discrepancy of findings</b>				
<b>Outcome of interest</b>	<b>Quantitative fidelity findings</b>		<b>Qualitative Interview findings</b>	<b>Convergence/ Discrepancy/ Silence</b>
Fidelity findings:	<b>Overall fidelity scores of SOLAS treatment delivery</b>	High fidelity (>80%) <ul style="list-style-type: none"> <li>• Direct Observations: 82.7%</li> <li>• Self-Report: 92.7%</li> <li>• Audio-Recordings: 81.7%</li> </ul>	Overall physiotherapists felt that their fidelity was good. Some adaptations and deviations were discussed as occurring in the delivery of the following aspects of the programme: <ul style="list-style-type: none"> <li>• Goal-setting (Introduction and Review, Review and Planning categories)</li> <li>• Education content</li> <li>• Exercise content</li> <li>• Use of programme materials</li> <li>• Dosage of session 1 (session duration)</li> </ul>	Convergence
	<b>SOLAS categories scoring below 80% fidelity</b>			
	<i>Materials</i>	Moderate fidelity (50-79%) <ul style="list-style-type: none"> <li>• Direct Observations: 72.1%</li> <li>• Audio-Recordings: 61.1%</li> </ul>		
	<i>Introduction and Review</i>	<ul style="list-style-type: none"> <li>• Audio-recordings: 76.2%</li> </ul>		
	<i>Review and Planning</i>	<ul style="list-style-type: none"> <li>• Direct Observations: 77.1%</li> <li>• Audio-Recordings: 69.8%</li> </ul>		
	<b>Fidelity of dose – sessions significantly different to intended dose</b>			
<i>Session 1</i>	<ul style="list-style-type: none"> <li>• Education duration: 58.9’*</li> <li>• Exercise duration: 31.4’*</li> </ul>			
Factors influencing	<b>Correlation between quantitative variables and fidelity scores</b>		<i>Theme 1: Physiotherapist knowledge and experience influenced delivery of SOLAS - education content</i>	Convergence



fidelity findings:	Physiotherapist Experience (years qualified)	<ul style="list-style-type: none"> <li>• Audio-recordings: -0.333 (p=0.011)***</li> </ul>		
	Physiotherapist Group Experience (years delivering group physiotherapy)	<ul style="list-style-type: none"> <li>• Self-report: -0.430 (p=0.018)***</li> </ul>		
	Physiotherapist Post-Training Evaluation Score (%)	<ul style="list-style-type: none"> <li>• Direct observations: 0.581 (p=0.003)**</li> <li>• Audio-recordings: 0.314 (p=0.018)***</li> </ul>	<i>Theme 1: Physiotherapist knowledge and experience influenced delivery of SOLAS - education content</i>	Convergence
	Group size (average numbers of participants present)	<ul style="list-style-type: none"> <li>• Direct observations: -0.434 (p=0.034)***</li> </ul>	<i>Theme 3: Group size influenced delivery of SOLAS – goal-setting, use of materials</i>	Convergence
	No corresponding quantitative data		<ul style="list-style-type: none"> <li><i>Theme 2: Individual needs influenced delivery of SOLAS - education, exercise, goal-setting</i></li> <li><i>Theme 4: Group dynamics influenced delivery of SOLAS - goal-setting</i></li> <li><i>Theme 5: Amount of education content influenced delivery of SOLAS – dosage (session duration)</i></li> <li><i>Theme 6: Resources/materials influenced delivery of</i></li> </ul>	Silence

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		<i>SOLAS – education and exercise content</i>	
<b>*p&lt;0.001, **p&lt;0.005, ***p&lt;0.05</b>			

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## DISCUSSION

The aim of this mixed methods study was to explore and evaluate treatment fidelity within a feasibility trial of a complex behaviour change intervention using multiple assessment methods. The study found good agreement between researcher-delivered direct observation and audio-recorded fidelity assessment methods, with lower agreement found between provider self-report and researcher-delivered methods. The intervention content was delivered overall with high fidelity, with some variation between physiotherapists and between certain intervention categories. The intervention dose was found to have deviated significantly from intended during the first session only. Subsequently, qualitative interviews with physiotherapists confirmed these fidelity findings. Finally, both qualitative and quantitative data showed that physiotherapists' knowledge and previous experience, as well as the group size, were factors that influenced their fidelity of intervention delivery. The qualitative data contributed further, and postulated additional participant and programme-level factors as aspects that also influenced the overall fidelity results.

Agreement between direct observations and audio-recordings for assessing the fidelity of treatment delivery was found to be excellent.<sup>40</sup> Agreement between both of these methods and provider self-report assessment was lower, as providers consistently rated themselves higher than the independent raters. These findings are perhaps unsurprising, as both direct observations and audio-recordings were rated by the same researcher, and numerous previous studies have shown that providers' subjective assessments of fidelity are often rated higher than independent assessments.<sup>27,28,41</sup> Taking direct observations as the commonly-cited 'gold standard',<sup>11,14,16</sup> these findings reinforce that self-report methods may not be the most accurate method for assessing fidelity in a complex behaviour change study. However, they may still have their place for recording data and also for enhancing fidelity to the protocol by serving as an aide memoire for providers.<sup>42</sup> Although direct observations and audio-recordings have their own limitations<sup>20,43</sup>, previous piloting of these assessment methods found that they were feasible and acceptable to physiotherapists.<sup>23</sup> Additionally, the good agreement between audio-recordings and direct observations found in this study suggests that audio-recordings may be a viable alternative with limited resources, as has been done in similar interventions.<sup>44</sup> However, where resources allow, a combination of multiple quantitative methods may provide the most comprehensive assessment of fidelity.

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3 One of the key study findings of this study was reinforcing the value of using mixed methods  
4 research for the assessment of fidelity. This approach was emphasised in the recent MRC  
5 guidelines for conducting process evaluations of complex interventions<sup>6</sup>, and is becoming  
6 increasingly used in the widespread implementation of evidence-based interventions<sup>45</sup> but  
7 does not yet appear to be common practice within fidelity assessments of behaviour change  
8 interventions.<sup>10,17</sup> The integration of quantitative and qualitative results enabled the  
9 triangulation of findings to provide a better overall picture of the fidelity of the SOLAS  
10 intervention and its influencing factors. The importance of the qualitative contribution to  
11 answering the ‘why’ question is evident in the fact that the physiotherapist interviews  
12 unearthed strong participant and programme-level factors associated with fidelity results that  
13 were not apparent from the quantitative data alone. Whilst this may be predominantly due to  
14 the focus of the quantitative analysis on physiotherapist-level variables which were chosen  
15 based on existing literature, the participant and programme-level factors identified by this  
16 analysis such as group dynamics or amount of programme content may have been difficult to  
17 quantitatively analyse to demonstrate association with fidelity results.  
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30 This study found that the factors that may influence the fidelity of an interventions’ delivery  
31 can occur on three levels – provider, participant and programme. Where previous studies  
32 have explored factors that have influenced fidelity of intervention delivery, many have  
33 focused solely on provider-level factors, demonstrating associations between fidelity and  
34 factors such as provider training or skills.<sup>15,17,31,35</sup> The findings of this study have valuable  
35 implications for future studies that aim to assess and enhance fidelity of similar interventions  
36 as they indicate that planning for fidelity should include considering potential influencing  
37 factors at each of these three levels. These results are consistent with recent conclusions by  
38 Masterson-Algar et al. in a stroke rehabilitation setting<sup>34</sup> who found that investigating  
39 fidelity within clinical trials should also take the individual needs of patients into account,  
40 and also concur with the findings of an education-based intervention that found the most  
41 common reason for adaptation within intervention delivery was insufficient time.<sup>46</sup>  
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51 On the physiotherapist-level, better knowledge of the intervention content and structure was  
52 found to positively correlate with quantitative fidelity scores, with a causative link  
53 established via the qualitative investigation. This echoes previous findings by Huijg et al.  
54 who showed that physiotherapist skill level was one of the most important predictors of  
55 fidelity.<sup>17</sup> A more targeted approach to enhancing fidelity in future interventions may  
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3 therefore be warranted, such as identifying physiotherapists at higher risk of lower fidelity  
4 using post-training evaluation scores and employing more focused fidelity assessment of  
5 delivery or further training for these providers,<sup>31</sup> as has been previously employed in similar  
6 interventions.<sup>10,44</sup> The results of the study also showed that physiotherapists with more  
7 experience of certain aspects tended to emphasise these at the expense of delivering other  
8 components as comprehensively as intended in the protocol. These experience-based  
9 adaptations invoke the well-established issue of adaptation versus fidelity. For years, research  
10 has debated the concept of fidelity versus adaptation, with the case made for both strict  
11 fidelity and for modifying interventions.<sup>47</sup> A third view is that both fidelity and adaptation  
12 are essential, and achieving an appropriate balance between both can allow an intervention to  
13 maximise its effectiveness, while being generalizable and flexible enough to be  
14 implementable.<sup>48,49</sup> To achieve this, our fidelity checklists included components that  
15 encouraged elements of treatment individualisation (e.g. individualised feedback regarding  
16 exercises). However, it may be that these checklists still did not allow for enough  
17 individualisation within delivery, an aspect that should be considered by other researchers  
18 seeking to conduct similar fidelity assessments.  
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31 A limitation of this study was the timing of the interviews, which did not allow a 'pure'  
32 convergent/triangulation design. Typically, the qualitative and quantitative methods occur  
33 concurrently in this design,<sup>24</sup> however, they were scheduled to take place after  
34 physiotherapists had experienced delivery of an entire six-week SOLAS intervention.  
35 Although a sequential explanatory design<sup>26</sup> could have been used, interviews were conducted  
36 within two weeks of the intervention completion in order to minimise recall bias, and it was  
37 not feasible to complete the qualitative analysis beforehand. Finally, this study mostly  
38 focuses on the adherence of delivery (e.g. intervention content) and does not address the  
39 *quality* or competence of delivery of SOLAS, or how it was delivered (e.g. interpersonal or  
40 communication style of the physiotherapist), as this is being addressed in a separate  
41 publication.  
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## 51 CONCLUSIONS

52 In process evaluations and fidelity assessments of large scale complex interventions it is often  
53 recommended to complete and report the results of the fidelity assessment before the trial  
54 outcomes so as not to bias reporting.<sup>50</sup> Future work will investigate the relationship between  
55 this evaluation of fidelity and the SOLAS feasibility trial outcomes (analysis currently  
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3 underway), enabling a potentially more insightful and accurate interpretation of findings.  
4 This study also has valuable implications for further research and the overall science of  
5 treatment fidelity as it contributes much-needed information to the limited current evidence  
6 for the application of fidelity assessment methods within the area of complex behaviour  
7 change. The findings have demonstrated how multiple quantitative methods can be used to  
8 assess the fidelity of a complex behaviour change intervention, and that a combination of  
9 methods may be most suitable, depending on their acceptability and available resources. We  
10 have also shown how the use of a mixed methods approach, integrating both quantitative and  
11 qualitative data, provides a more insightful understanding of the factors influencing fidelity.  
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## **AUTHORS' CONTRIBUTION**

ET conceptualized and designed the study and conducted the data collection and analysis. JM and DAH provided guidance on the design. DAH is the principal investigator of the SOLAS trial and obtained funding for this study within the trial. All authors provided methodological consultation and were involved in substantial contributions to reviewing of the drafts. All authors approved the final version of the manuscript.

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## **CONFLICTS OF INTEREST**

None



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## Supplementary Files

Supplementary File 1: Physiotherapist baseline characteristics										
	Wave 1				Wave 2					
Physiotherapy Site	A	B	C	D	A	B	C	E	F	G
Physiotherapist	A1	B1	C1	D1	A1	B2	C2	E1	F1	G1
Gender	F	F	F	M	F	F	F	F	F	F
Experience (years qualified)	5	25	8	12	5	25	10	6	19	11
Group experience (years delivering group physiotherapy)	1	3	8	2	1	10	3	1	15	7
Post-training evaluation score (%)	74%	81.5%	90.5%	83.4%	74%	88.5%	81.8%	81.2%	78.1%	94.4%
Previous training in similar interventions (Y/N)	N	Y	Y	Y	N	Y	Y	Y	Y	Y
F= female, M=male, Y=yes, N=no										

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<b>Supplementary File 2: Agreement between assessment methods</b>				
	Direct Observation v Self-Report (n=24)	Direct Observation v Audio- Recordings (n=24)	Audio-Recordings v Self-Report (n=60)	Audio-Recordings Rater 1 v Rater 2 (Inter-rater reliability) (n=12)
<b>Overall agreement</b>	74.6%	86.6%	75.4%	84.6%
<b>% Agreement per category:</b>				
<b>Materials</b>	74.5%	82.67%	70.1%	84.6%
<b>Introduction and Review</b>	65.3%	86.5%	57%	81.6%
<b>Education</b>	84.6%	90.3%	87.3%	76.7%
<b>Exercise</b>	70.8%	86%	78%	83.3%
<b>Review and Planning</b>	50%	76.2%	46%	100%

# BMJ Open

## Using mixed methods to assess fidelity of delivery and its influencing factors in a complex self-management intervention

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<b>Primary Subject Heading</b>:	Research methods
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Keywords:	implementation fidelity, PRIMARY CARE, complex interventions, behaviour change

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Manuscripts

**Title**

Using mixed methods to assess fidelity of delivery and its influencing factors in a complex self-management intervention

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**Word count**

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**ABSTRACT:**

**Objectives and design:** Despite an increasing awareness of the importance of fidelity of delivery within complex behaviour change interventions, it is often poorly assessed. This mixed methods study aimed to establish the fidelity of delivery of a complex self-management intervention and explore the reasons for these findings using a convergent/triangulation design.

**Setting:** Feasibility trial of the Self-management of Osteoarthritis and Low back pain through Activity and Skills (SOLAS) intervention, delivered in primary care physiotherapy.

**Methods and outcomes:** 60 SOLAS sessions were delivered across seven sites by nine physiotherapists. Fidelity of delivery of pre-specified intervention components was evaluated using 1) audio-recordings (n=60), direct-observations (n=24) and self-report checklists (n=60) and 2) individual interviews with physiotherapists (n=9). Quantitatively, fidelity scores were calculated using percentage means and standard deviations of components delivered. Associations between fidelity scores and physiotherapist variables were analysed using Spearman's correlations. Interviews were analysed using thematic analysis to explore potential reasons for fidelity scores. Integration of quantitative and qualitative data occurred at an interpretation level using triangulation.

**Results:** Quantitatively, fidelity scores were high for all assessment methods; with self-report (92.7%) consistently higher than direct-observations (82.7%), or audio-recordings (81.7%). There was significant variation between physiotherapists' individual scores (69.8% - 100%). Both qualitative and quantitative data (from physiotherapist variables) found that physiotherapists' knowledge (Spearman's association at  $p=0.003$ ) and previous experience ( $p=0.008$ ) were factors that influenced their fidelity. The qualitative data also postulated participant-level (e.g. individual needs) and programme-level factors (e.g. resources) as additional elements that influenced fidelity.

**Conclusion:** The intervention was delivered with high fidelity. This study contributes to the limited evidence regarding fidelity assessment methods within complex behaviour change interventions. The findings suggest a combination of quantitative methods is suitable for the

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3 assessment of fidelity of delivery. A mixed methods approach provided a more insightful  
4 understanding of fidelity and its influencing factors.  
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### 8 **Article summary – strengths and limitations**

- 9
- 10 • This mixed methods investigation of fidelity of delivery and its influencing factors
- 11 provides valuable information on fidelity assessment methods and factors to be
- 12 considered in developing and evaluating complex behaviour change interventions
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- 14 • The novel use of mixed methods to assess fidelity in this study enabled increased
- 15 certainty in findings where qualitative data corroborated the quantitative results
- 16
- 17
- 18 • This study does not explore the fidelity of the *quality* of delivery (e.g. therapist
- 19 competence) or specific behaviour change techniques (BCTs) which will be reported in a
- 20 separate publication
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# USING MIXED METHODS TO ASSESS FIDELITY OF DELIVERY AND ITS INFLUENCING FACTORS IN A COMPLEX SELF-MANAGEMENT INTERVENTION

## INTRODUCTION

Fidelity of delivery is an important, yet often overlooked aspect of behaviour change interventions and has been defined as the degree to which an intervention, treatment or program is delivered as intended by the intervention developers.<sup>1,2</sup> Without adequately addressing fidelity in behaviour change research, it is uncertain that changes observed in study outcomes are due to the influence of the independent variable (the intervention being investigated) and not due to variability in its implementation, e.g. extraneous elements that may have been added (either accidentally or purposely), or essential elements of the intervention that were omitted.<sup>3</sup> In particular, as behaviour change interventions are often complex interventions that typically involve several components with the potential to affect or influence outcomes separately, it is especially important to incorporate adequate fidelity planning and assessment into the development of interventions of this nature.<sup>4</sup>

Despite a recent increased emphasis on improved assessment and reporting of what happens within complex behaviour change interventions,<sup>5,6</sup> fidelity is still poorly addressed within this context, with few examples of fidelity being assessed comprehensively or reported adequately.<sup>7-9</sup> Where studies have assessed fidelity within a behaviour change healthcare context, there is often limited exploration of the factors that might have influenced that fidelity.<sup>10,11</sup> Previous work that *has* specifically examined influencing factors in areas of public health, obesity and stroke research found that provider-level variables, such as experience, knowledge or skills, may influence fidelity of delivery.<sup>12-15</sup> Although the use of both quantitative and qualitative methods has been previously recommended to comprehensively assess fidelity,<sup>16-18</sup> this guidance is not consistently followed. Consequently, the use of quantitative methods in isolation may not allow for exploration of the factors influencing fidelity, knowledge of which could improve how fidelity is enhanced and assessed in future similar interventions.<sup>19</sup> For example, French et al.<sup>11</sup> used audio-recordings and self-report methods to assess the fidelity of delivery of an educational

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3 intervention for general practitioners. The authors acknowledged that the quantitative study  
4 design did not allow them to explore the reasons for variations in fidelity scores found.  
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8 According to existing guidelines for addressing fidelity within behaviour change research  
9 developed by the National Institutes of Health Behaviour Change Consortium (NIHBCC),<sup>18</sup>  
10<sup>,20</sup> the fidelity of delivery of the intervention by providers is one particularly important aspect  
11 of fidelity. This aspect considers strategies that enhance the fidelity of delivery (e.g. using  
12 treatment manuals or intervention protocols) and methods that assess this delivery (e.g.  
13 provider self-report, audio or video-recorded observations and direct *in vivo* observations).  
14 However, although previous research has advocated a combination of these strategies in order  
15 to assess fidelity in-depth,<sup>21,22</sup> limited examples exist within the literature. Additionally, few  
16 studies have explored the relationship between these methods, and the accuracy of potentially  
17 more feasible methods against the ‘gold standard’ of direct observations using pre-specified  
18 criteria<sup>23</sup> has been poorly investigated.<sup>18,19,24</sup> As a result, there is little evidence to justify  
19 the selection of one method over another, or to inform the use of multiple methods  
20 simultaneously.  
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24 The current study is set within the context of the SOLAS (Self-Management of Osteoarthritis  
25 and Low back pain through Activities and Skills) feasibility trial [ISRCTN49875385].<sup>25</sup> The  
26 trial aims to evaluate the feasibility of providing the SOLAS intervention (experimental  
27 group) to promote self-management for patients with osteoarthritis (OA) of the hip/ knee  
28 and/or chronic low back pain (CLBP) compared to usual physiotherapy, which will serve as  
29 the pragmatic control group in order to determine the feasibility of moving to a full scale trial  
30 by following the MRC guidelines. The intervention consists of six weekly sessions of 90  
31 minutes to be delivered by a primary care physiotherapist to a group of six to eight people.  
32 Each session is divided into education and exercise sections (each approximately 45 minutes  
33 in duration), and further split into categories as detailed in an intervention manual<sup>25,26</sup>  
34 (summarised in Table 1). Prior to participation, physiotherapists were provided with the  
35 manual during a two-day training course where background variables were collected, in  
36 addition to a post-training assessment.<sup>26</sup> Details of the development and testing of the fidelity  
37 protocol used in this study are described elsewhere.<sup>27</sup> This study also does not explore the  
38 fidelity of the *quality* of delivery (e.g. therapist competence) or specific behaviour change  
39 techniques (BCTs) which will be reported elsewhere.  
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3 The aim of this study was to establish the fidelity of delivery of a complex behaviour change  
4 intervention and the reasons for these findings using a mixed methods approach. Specifically,  
5 the study objectives were:  
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- 8 1) To evaluate the agreement of multiple methods for assessing fidelity of delivery
- 9 2) To establish the fidelity of delivery of the SOLAS complex behaviour change  
10 intervention
- 11 3) To explore the potential factors that may have influenced these fidelity results  
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<b>Session Number</b>	1	2	3	4	5	6
Self-management behaviours/ skills targeted	<ul style="list-style-type: none"> <li>Physical activity</li> <li>Goal-setting</li> </ul>	<ul style="list-style-type: none"> <li>Pacing (balancing activity/rest)</li> <li>Physical activity</li> <li>Goal-setting</li> </ul>	<ul style="list-style-type: none"> <li>Balanced weight/ healthy diet</li> <li>Physical activity</li> <li>Goal-setting</li> </ul>	<ul style="list-style-type: none"> <li>Managing pain with pain relief</li> <li>Physical activity</li> <li>Goal-setting</li> </ul>	<ul style="list-style-type: none"> <li>Managing mood (with relaxation)</li> <li>Physical activity</li> <li>Goal-setting</li> </ul>	<ul style="list-style-type: none"> <li>Long-term management</li> <li>Physical activity</li> <li>Goal-setting</li> </ul>
<b>Session Structure</b>						
<b>Section</b>	<b>Category</b>	<b>Aim/content</b>				<b>Intended Duration</b>
Education	Materials	Participants are provided with materials intended to supplement and enhance their understanding and uptake of skills, such as pedometers, participant activity diaries, participant handbook and relaxation CDs				45 minutes
	Introduction and Review	At the start of each session the physiotherapist reviews goals and action plans with participants and problem-solving where necessary				
	Education	Physiotherapist facilitates a group discussion on the targeted self-management skill/behaviour of the session using Powerpoint slides and projector to provide information				

	Review and Planning	Before the session concludes, the physiotherapist briefly recaps participants' planned activity levels and action plans for the week ahead									
Exercise	Exercise	Participants are provided with an opportunity to attempt and practice a variety of exercises									45 minutes
<b>Samples involved</b>											
	<b>Wave 1</b>				<b>Wave 2</b>						<b>Total n=</b>
Physiotherapy Site code	A	B	C	D	A	B	C	E	F	G	<b>10 (7)*</b>
Physiotherapist code	A1	B1	C1	D1	A1	B2	C2	E1	F1	G1	<b>9**</b>
Number of participants recruited	4	6	4	2	4	4	5	4	7	5	<b>45</b>
Sessions delivered	6	6	6	6	6	6	6	6	6	6	<b>60</b>
Direct Observations	3	3	3	3	2	2	3	2	1	2	<b>24 (40%)</b>
Self-Report	6	6	6	6	6	6	6	6	6	6	<b>60 (100%)</b>
Audio-Recordings (rater 1)	6	6	6	6	6	6	6	6	6	6	<b>60 (100%)</b>
Audio-Recordings (rater 2)	3	3	3	3	0	0	0	0	0	0	<b>12 (20%)</b>
**Seven sites were involved in total, but three of these delivered the intervention in both waves											
*One physiotherapist delivered the intervention in both waves											

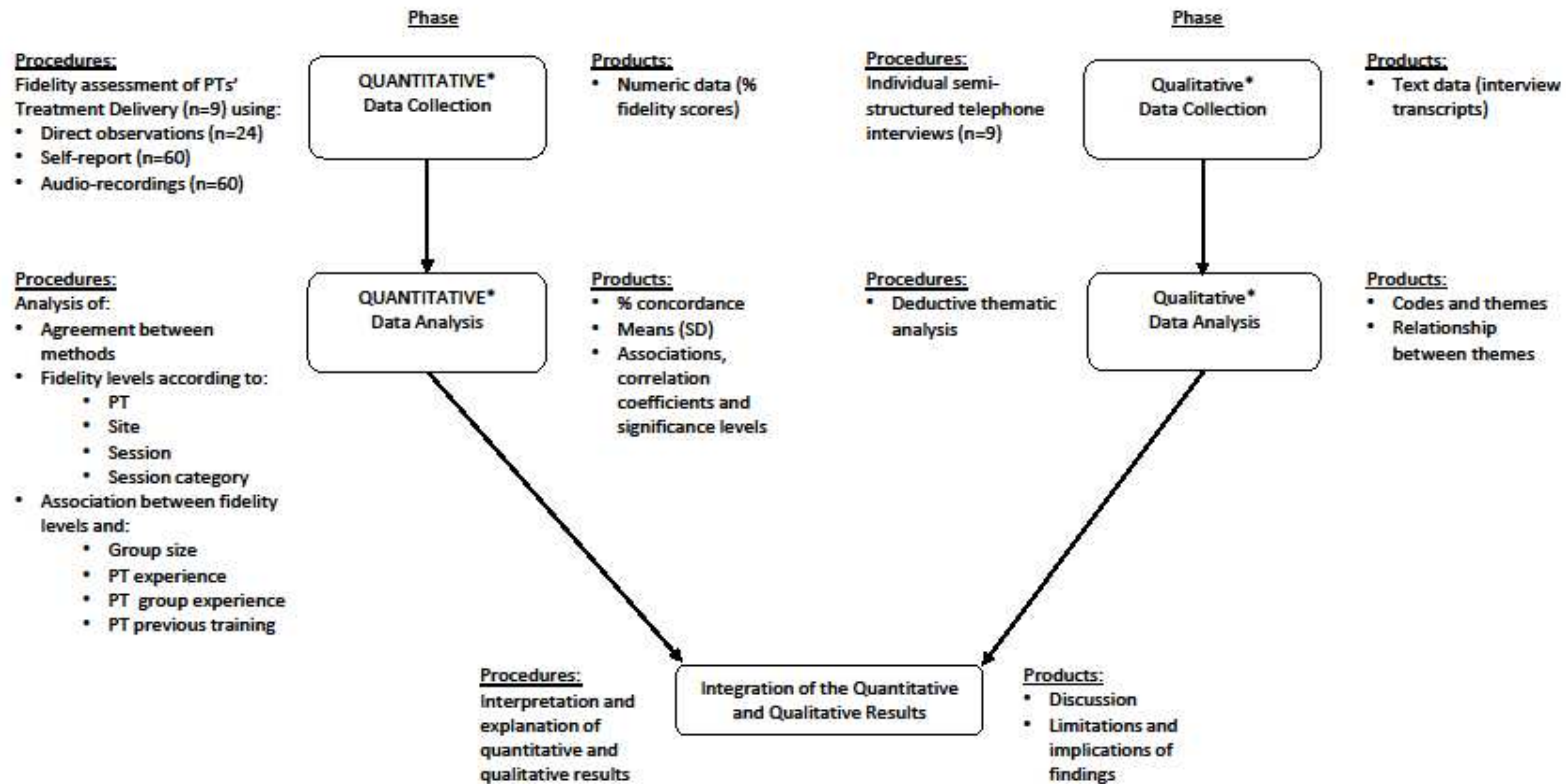
## METHODS

### Ethics

Ethical approval for this study was granted by University College Dublin's Human Research Ethics Committee (LS-13-54). Written informed consent was obtained from all physiotherapists and participants prior to any observations or interviews.

### Design

This observational study was a convergent/triangulation mixed methods design.<sup>28</sup> This mixed methods approach was chosen as it was felt that thorough integration of findings from both quantitative and qualitative methods would achieve a more comprehensive answer to the study questions by enabling the methods to be 'greater than just the sum of their parts'.<sup>29</sup> Figure 1 graphically illustrates the study design, outlining the sequence of research activities, the priority of the methods and the stage at which integration occurred.<sup>30</sup>



\*capitalisation represents weighting or priority, PT = physiotherapist, SD = standard deviation

Figure 1: Diagrammatic representation of mixed methods convergent/triangulation design

## Quantitative phase

### Study sample and procedure:

Data were collected during two of the three waves of the SOLAS feasibility trial (Table 1), representing 71% of the overall trial data. Fidelity of delivery in this study refers to the assessment of both the delivery of session content, i.e. providers deliver the session categories and components as intended (summarised in Table 1) (fidelity of content) and session duration, i.e. providers deliver the session as long as intended (fidelity of duration). Following pilot testing, it was decided to conduct 24 (40% of sessions) randomly selected direct observations (rated by ET), 60 (100%) self-report (rated by the physiotherapists) and 60 (100%) audio-recordings (rated by ET) to assess fidelity of delivery using a-priori checklists (Supplementary File 1) that had been previously found to be feasible for use.<sup>27</sup> To assess inter-rater reliability, 12 sessions (20%) were rated by a second independent rater (AK).<sup>10</sup> Checklists consisted of approximately 25 components for each session, structured according to the SOLAS categories as detailed in Table 1. Components for each session were chosen to address each element specified in the SOLAS intervention manual (summarised in Table 1)<sup>25,26</sup> to be delivered during that session. Each component was rated as 'Yes/Present' equating to a score of two points, 'No/Absent' (zero points), or 'Attempted' (one point). Session duration was documented by all methods, and attendance was recorded by self-report.

### Data analysis:

Fidelity data analysis was consistent with standard procedures<sup>19,31,32</sup> using SPSS v20. Specifically, levels of agreement between methods and inter-rater reliability of audio-recorded data were assessed using percentage concordance. Overall mean fidelity of content scores (i.e. percentage of manual-specified components delivered as intended) and fidelity scores according to physiotherapy site, physiotherapist, session and session category were obtained by calculating total actual scores (delivered components) as a percentage of the total possible score (intended components). Means data were compared using ANOVAs and Kruskal-Wallis tests. Fidelity of duration was established by calculating the difference between the actual and the intended session duration using a one-sample Wilcoxon test. Levels of fidelity were interpreted as previously reported in the literature, with 80-100% adherence interpreted as 'high' fidelity, 51-79% as 'moderate' and 0-50% as 'low' fidelity.<sup>3,33,34</sup> Finally, the relationship between fidelity scores and 1) the number of participants present (group size) and 2) physiotherapist variables, i.e. experience (years qualified), group



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3 experience (years delivering group physiotherapy), knowledge of intervention (post-training  
4 evaluation score) and previous relevant training (Supplementary File 2), were calculated  
5 using Spearman's correlation coefficient and Mann-Whitney U test. These physiotherapist  
6 variables were chosen for reasons described in the introduction.  
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### 11 **Qualitative phase**

12 The aim of the qualitative phase was to explore physiotherapists' opinions of fidelity of  
13 intervention delivery and the factors that they felt may have influenced their fidelity.  
14 Individual semi-structured telephone interviews were conducted by an experienced  
15 qualitative researcher (SG) with each physiotherapist (n=9) within two weeks of intervention  
16 delivery completion. A topic guide with specific questions and probes related to fidelity was  
17 developed by the corresponding author (ET) (Supplementary File 3). Interviews were audio-  
18 recorded and transcribed verbatim. Deductive thematic analysis was used to analyse the  
19 interviews as it is a flexible method that works with a range of research questions, including  
20 understanding people's experiences of programmes and health-care interventions.<sup>36</sup>  
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29 Meaningful units of text were highlighted within each interview, then summarised and coded.  
30 Codes dealing with similar issues were grouped across all interviews and refined into themes.  
31 The reliability of themes was established by a second reviewer (AK) who independently  
32 analysed a randomly selected sample of 50% of the transcript extracts using the coding  
33 framework. Percentage agreement was determined between the reviewers' respective coding  
34 of extracts. If agreement was less than 70%, consensus on conflicting decisions was obtained  
35 through discussion.<sup>37</sup>  
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### 43 **Integration**

44 Integration of quantitative and qualitative data occurred at an interpretation level using  
45 triangulation methodology. Specifically, a meta-matrix was created to facilitate comparison  
46 of the findings (Table 5).<sup>38</sup> This involved presenting the quantitative data in a tabular format  
47 alongside summarised qualitative themes, which enabled a transparent approach to  
48 determining convergence, discrepancy or silence across the findings of the data sets.<sup>39</sup>  
49 Convergence was defined as general agreement between the data sets on the element of  
50 comparison (e.g. overall quantitative fidelity score compared to the majority of  
51 physiotherapist opinions of their fidelity levels), while discrepancy was defined as general  
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3 disagreement between the data sets on the element of comparison.<sup>39</sup> Silence was defined as  
4 where one set of results addressed a theme or example, but the other set of  
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6 results did not yield any relevant data.<sup>39</sup>  
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## 10 11 RESULTS

### 12 13 14 15 **Quantitative findings**

#### 16 Agreement:

17 Agreement between direct observations and self-report was 74.6%, 75.4% between self-  
18 report and audio-recordings (rater 1) and 86.6% between direct observations and audio-  
19 recordings (rater 1). Inter-rater reliability of audio-recordings (rater 1 vs rater 2) was 81.3%.  
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21 Further detail is provided in Supplementary File 4.  
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#### 26 Fidelity of content:

27 Fidelity was found to be high in all assessment methods, with a mean score of 81.7% (range  
28 of 61.1% - 95.8%) for the audio-recordings, 92.7% (85.2% - 96%) for the self-report and  
29 82.7% (72.1% - 100%) for the direct observations. Table 2 details the fidelity results for each  
30 method with scores below 80 (cut-off for 'high' fidelity) shaded. Significant differences  
31 between physiotherapists' individual fidelity scores were found. Fidelity scores were also  
32 found to differ significantly according to the session category (e.g. the category 'Materials'  
33 was delivered with significantly less fidelity than the 'Education' category).  
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<b>Table 2: Fidelity results calculated from % totals</b>			
	<b>Direct Observations (DO)</b>	<b>Self-Report (SR)</b>	<b>Audio 1 (AO)</b>
	<b>% (SD)</b>	<b>% (SD)</b>	<b>% (SD)</b>
<b>Total % mean fidelity score (SD)</b>	82.7% (10)	92.7% (6.4)	81.7% (12)
<b>% mean fidelity score per session (SD)***</b>			
1	88.8% (5.24)	95% (4.5)	91.6% (4.5)
2	82.8% (5.7)	92% (6.9)	86.8% (10.5)
3	85.6% (12.9)	96% (4.2)	81.4% (10.6)
4	83.3% (14.4)	90.9% (8.3)	75% (14)
5	74.1% (11.9)	89.4% (8.1)	78.7% (11)
6	82% (9.6)	92.7% (3.78)	74.9% (12)
<b>% mean fidelity score per site (SD)***</b>			
A (delivered twice, same physiotherapist)	78.7% (7.6)	95% (5.4)	81.3% (11.5)
B (delivered twice, two physiotherapists)	76.7% (5.6)	92.8% (5.3)	71.1% (10)
C (delivered twice, two physiotherapists)	84.8% (11.8)	91.8% (7.7)	84.9% (8.1)
D	87.2% (4)	93.2% (2.9)	87.1% (4.4)
E	83.1% (13)	94.3% (3.8)	88.3% (8.7)

F	72.5%	85.2% (9.6)	72.9% (15)
G	100% (0)	94.7% (4.4)	92.8% (5.4)
<b>% mean fidelity score per category (SD)*</b>			
Materials	72.1% (19.4)	86% (17)	61.1% (29.6)
Introduction and Review	82.6% (16.3)	92.9% (12.8)	76.2% (24.5)
Education	93.3% (8.6)	97.1% (6.6)	95.4% (6.9)
Exercise	80.4% (14)	95.4% (7.1)	82.4% (13)
Review and Planning	77.1% (33)	90.8% (21.6)	69.8% (39.6)
<b>% mean fidelity score per physio (SD)**</b>			
A1	78.8% (7.6)	95.1% (5.4)	81.3% (11.5)
B1	76.1% (7.9)	92.2% (7.2)	72.3% (9.3)
B2	77.5% (0.4)	93.4% (3)	72.6% (12.5)
C1	93.4% (2)	85.2% (4.6)	91% (3.5)
C2	76.2% (11)	98.5% (1.9)	78.8% (6.6)
D1	87.2% (4)	93.2% (2.9)	87.1% (4.4)
E1	83.1% (13)	94.3% (3.8)	88.3% (8.7)
F1	72.5%	85.2% (9.6)	69.8% (14.7)
G1	100% (0)	94.7% (4.4)	95.8% (5.4)
*Significant differences between Categories according to DO (p=0.007), SR (p<0.001) and AO (p<0.001)			
** Significant differences between Physiotherapists according to DO (p=0.019), SR (p=0.004) and AO (p<0.001)			
***Significant differences between Sites (p<0.001) and between Sessions (p=0.007) according to AO, not significantly different			

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according to DO and SR.  
Shaded areas = scores < 80%

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### Fidelity of duration:

All methods found a statistically significant difference between the actual duration of the exercise component and its intended duration of 45 minutes (Supplementary File 5). When this was analysed for each individual session for all methods combined, a statistically significant difference ( $p < 0.001$ ) was only found for Session 1 between the actual and intended duration. The difference between the actual and intended duration for all other sessions was not found to be statistically significant ( $p > 0.05$ ).

### Group size – participants in attendance:

The average numbers of participants present for all groups across all sessions was 3, with an SD of 1.3 (Supplementary File 6). Overall, group attendance ranged from one to six participants for any session across both waves. The total number of participants recruited for each group was significantly different between physiotherapists (e.g. seven participants were recruited for the group delivered by physiotherapist F1 compared to only two recruited for the group delivered by D1), as were the numbers of participants present (average group size).

The size of groups did not differ significantly between sessions.

### Factors associated with fidelity:

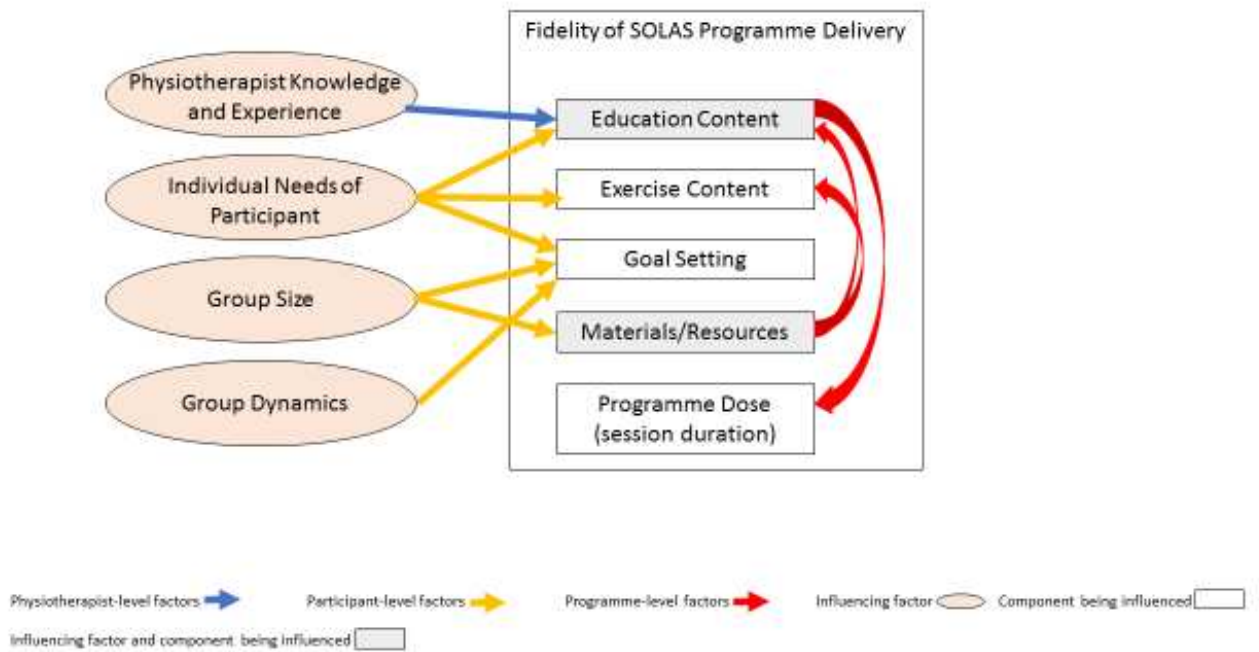
Both direct observation and audio-recorded data showed a significant correlation between fidelity scores and the physiotherapists' post-training evaluation scores. Direct observation data also found a significant negative correlation between group sizes and the fidelity scores. Physiotherapist years qualified and experience of delivering groups were found to have significant, negative correlations with fidelity scores for the audio-recorded and self-report data respectively (Table 3).

Variable	Direct Observations	Self-Report	Audio-Recordings	Statistical Test
Group size (number present)	-0.434 ( $p=0.034$ )*	-0.215 ( $p=0.98$ )	-0.193 ( $p=0.151$ )	Spearman's $r$ ( $p$ -value)
Physiotherapist experience (years qualified)	-0.09 ( $p=0.676$ )	-0.186 ( $p=0.154$ )	-0.346 ( $p=0.008$ )*	

Physiotherapist group experience (years delivering group physiotherapy)	0.171 (p=0.424)	-0.364 (p=0.004)**	0.136 (p=0.312)	
Physiotherapist Post-Training Evaluation Score (%)	0.581 (p=0.003)**	-0.152 (p=0.245)	0.314 (p=0.018)*	
Physiotherapist previous relevant training (yes/no)	$U=33$ (p=0.302)	$U=201$ (p=0.107)	$U = 243$ (p=0.840)	Mann-Whitney U (p-value)
*p is significant at $p<0.05$ , ** $p<0.005$				

### Qualitative findings

Inter-rater reliability of coding achieved 81.6% agreement. Overall, physiotherapists felt that they had delivered the programme with good fidelity. All physiotherapists discussed some deviations from the protocol or adaptations made during delivery, i.e. goal-setting was found to be challenging to complete as intended. Other adaptations either concerned difficulties with use of programme materials (e.g. using the projector) as intended or providing additional information during the education content. Five physiotherapists also discussed deviation from protocol in relation to duration, mostly during the first session, with one stating that her *'time management around the education wasn't always exactly what it should have been'* (B1, transcript line 278-286). In terms of factors that influenced fidelity (i.e. reasons discussed for the aforementioned adaptations and deviations), six themes were found that were structured into three levels of factors – physiotherapist, participant and programme-level (Figure 2).



**Figure 2:** Visual representation of themes of qualitative interviews – factors influencing fidelity of SOLAS delivery

At the physiotherapist level, eight of the nine physiotherapists felt that knowledge of the content of the SOLAS programme facilitated their delivery of the education session and made it easier. Conversely, deviations from protocol within the education content discussed by six physiotherapists were due to the provision of additional information which was influenced by their previous experiences of delivering similar groups (e.g. talking more about pain pathophysiology because of previous classes delivered on this topic). This formed the theme '*Physiotherapist knowledge and experience influenced delivery of SOLAS - education content*'.

At the participant level, five physiotherapists felt that participants' individual needs such as their understanding of content or language literacy levels influenced the delivery of education and exercise components and that adaptation sometimes occurred in response to these needs, creating the theme of '*Individual needs influenced delivery of SOLAS - education, exercise, goal-setting*'. The number of participants present was discussed by seven physiotherapists as another participant-level factor that influenced fidelity of delivery and formed the participant-



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3 level theme of '*Group size influenced delivery of SOLAS - goal-setting, use of materials*'. A  
4 further participant-level theme was '*Group dynamics influenced delivery of SOLAS - goal-*  
5 *setting*' as four physiotherapists felt that groups with good dynamics and interaction between  
6 participants led to better group discussions and better facilitation of goal setting.  
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11 The '*Amount of education content influenced delivery of SOLAS – duration* was a  
12 programme-level factor discussed by six physiotherapists, who felt that the amount of  
13 education content that was involved in the first session led to more time spent on the  
14 education aspect than intended as per protocol. Finally, all nine physiotherapists believed that  
15 the good resources (e.g. booklets and handouts, venue space) enhanced and facilitated the  
16 delivery of the programme as intended and that occasionally poor or problematic resources  
17 (e.g. lack of venue security) negatively influenced the delivery of the programme as intended.  
18 This created the theme '*Resources/materials influenced delivery of SOLAS – education and*  
19 *exercise content*'. Exemplary quotes are provided in Table 4.  
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<b>Factor level</b>	<b>Theme</b>	<b>Exemplary quote (Physiotherapist code, transcript line)</b>
<b>Physiotherapist</b>	Physiotherapist knowledge and experience influenced delivery of SOLAS - education content	<i>'In my previous experience I would have done a lot more actually on the pain side of things...so in my previous class I would have had, you know, maybe one full class on maybe pain perception and, kind of, the influence of emotion and feelings...so I think I would have probably maybe talked a lot more around that pain section than maybe somebody else would have'. (C1, 75-99)</i>
<b>Participant</b>	Individual needs influenced delivery of SOLAS - education, exercise, goal-setting	<i>'People don't like writing them [action plans] there and then you know with pencils given and whatever - yes it's very hard to get people to write down things like that....Where I work there is a lot of people health literacy is very low...so therefore that's a challenge for them...so I tend to be very careful about pushing it out really' (F1, 141-187)</i>
<b>Participant</b>	Group size influenced delivery of SOLAS – goal-setting, use of materials	<i>'The only thing I might find a little bit hard would be the goal setting. I suppose you'd - that would be a bit more challenging because you'd have more numbers in the group' (G1, 118-132)</i>
<b>Participant</b>	Group dynamics influenced delivery of SOLAS - goal-setting	<i>'People were willing to engage you know as a group, in their goals.....so that made it very easy that we didn't actually have any clients that weren't willing to talk in the group, so it was very much an interactive group' (E1, 225-231)</i>
<b>Programme</b>	Amount of education content influenced delivery of SOLAS – duration	<i>'I found the content in week one was nearly too much... by the time I finished talking and ran through the exercises, the hour and a half was finished. And so nobody actually practiced any of the exercises on the first day' (B2, 96-106)</i>
<b>Programme</b>	Resources/materials	<i>'The slides didn't work for me this time....You can't lock that room.... once or twice I didn't</i>

	influenced delivery of SOLAS – education and exercise content	<p><i>bring the laptop at all and I just had to print it out, all of the slides on A4 laminate and so we talked all the slides....</i> ' (F1, 207-240)</p> <p><i>'I think I only left out maybe three [exercise] stations, something like that. Because we didn't have a bouncer and...we didn't have a bed'</i> (C1, 113-121)</p> <p><i>'Nothing but positive feedback for all the content and the-the resources...I just think they complimented the - the education fantastically, I just thought they added much more to the programme than not having these resources.'</i> (E1, 414-415)</p>
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### **Integrating qualitative and quantitative findings**

Each theme was further analysed according to the quantitative data comparing physiotherapists who scored 'high' (i.e.  $\geq 80\%$ ; physiotherapists D1, C1, E1 and G1) to those who scored 'moderate' (i.e.  $\geq 50-79\%$ ; B1, B2, C2 and F1). Physiotherapist A1 was not included in this analysis as her score was categorised as 'moderate' by direct observations and 'high' by audio-recorded data at 78.7% and 81.3% respectively. A difference between these physiotherapist groups was found in only one theme, '*Group size influenced delivery of SOLAS*'. Physiotherapists who scored higher on the fidelity assessments (average group size of 2.5 participants), believed it was easier to deliver goal-setting as intended with smaller groups. Conversely, physiotherapists with moderate fidelity scores (average group size of 3.7 participants) felt it was harder to facilitate goal-setting as intended with less numbers and believed it would be easier with bigger groups due to better engagement and group discussion. Further details of the triangulation are provided in Table 5 where a meta-matrix was used to compare between findings from both datasets. For the most part, convergence was found between the qualitative and quantitative data, though four qualitative themes relating to influencing factors had no corresponding quantitative data (silence). No areas of discrepancy were found.

<b>Table 5: Triangulation of quantitative and qualitative results – convergence and discrepancy of findings</b>				
<b>Outcome of interest</b>	<b>Quantitative fidelity findings</b>		<b>Qualitative interview findings</b>	<b>Convergence/ Discrepancy/ Silence</b>
Fidelity findings:	<b>Overall fidelity of content scores</b>	High fidelity (>80%) <ul style="list-style-type: none"> <li>• Direct Observations: 82.7%</li> <li>• Self-Report: 92.7%</li> <li>• Audio-Recordings: 81.7%</li> </ul>	Overall physiotherapists felt that their fidelity was good. Some adaptations and deviations were discussed as occurring in the delivery of the following aspects of the programme: <ul style="list-style-type: none"> <li>• Goal-setting (Introduction and Review, Review and Planning categories)</li> <li>• Education content</li> <li>• Exercise content</li> <li>• Use of programme materials</li> <li>• Duration of session 1</li> </ul>	Convergence
	<b>SOLAS categories scoring below 80% fidelity</b>			
	<i>Materials</i>	Moderate fidelity (50-79%) <ul style="list-style-type: none"> <li>• Direct Observations: 72.1%</li> <li>• Audio-Recordings: 61.1%</li> </ul>		
	<i>Introduction and Review</i>	<ul style="list-style-type: none"> <li>• Audio-recordings: 76.2%</li> </ul>		
	<i>Review and Planning</i>	<ul style="list-style-type: none"> <li>• Direct Observations: 77.1%</li> <li>• Audio-Recordings: 69.8%</li> </ul>		
	<b>Fidelity of duration – sessions significantly different to intended duration</b>			
<i>Session 1</i>	<ul style="list-style-type: none"> <li>• Education duration: 58.9’*</li> <li>• Exercise duration: 31.4’*</li> </ul>			
Factors influencing	<b>Correlation between quantitative variables and fidelity scores</b>		<i>Theme 1: Physiotherapist knowledge and experience influenced delivery of SOLAS - education content</i>	Convergence

fidelity findings:	Physiotherapist Experience (years qualified)	<ul style="list-style-type: none"> <li>• Audio-recordings: -0.333 (p=0.011)***</li> </ul>		
	Physiotherapist Group Experience (years delivering group physiotherapy)	<ul style="list-style-type: none"> <li>• Self-report: -0.430 (p=0.018)***</li> </ul>		
	Physiotherapist Post-Training Evaluation Score (%)	<ul style="list-style-type: none"> <li>• Direct observations: 0.581 (p=0.003)**</li> <li>• Audio-recordings: 0.314 (p=0.018)***</li> </ul>	<i>Theme 1: Physiotherapist knowledge and experience influenced delivery of SOLAS - education content</i>	Convergence
	Group size (average numbers of participants present)	<ul style="list-style-type: none"> <li>• Direct observations: -0.434 (p=0.034)***</li> </ul>	<i>Theme 3: Group size influenced delivery of SOLAS – goal-setting, use of materials</i>	Convergence
	No corresponding quantitative data			<i>Theme 2: Individual needs influenced delivery of SOLAS - education, exercise, goal-setting</i> <i>Theme 4: Group dynamics influenced delivery of SOLAS - goal-setting</i> <i>Theme 5: Amount of education content influenced delivery of SOLAS – duration</i> <i>Theme 6: Resources/materials influenced delivery of</i>

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		<i>SOLAS – education and exercise content</i>	
*p<0.001, **p<0.005, ***p<0.05			

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## DISCUSSION

The aim of this mixed methods study was to explore and evaluate fidelity of delivery within a feasibility trial of a complex behaviour change intervention using multiple assessment methods. The study found good agreement between researcher-delivered direct observation and audio-recorded fidelity assessment methods, with lower agreement found between provider self-report and researcher-delivered methods. The intervention content was delivered overall with high fidelity, with some variation between physiotherapists and between certain intervention categories. The intervention duration was found to have deviated significantly from intended during the first session only. Subsequently, qualitative interviews with physiotherapists confirmed these fidelity findings. Finally, both qualitative and quantitative data showed that physiotherapists' knowledge and previous experience, as well as the group size, were factors that influenced their fidelity of intervention delivery. The qualitative data contributed further, and postulated additional participant and programme-level factors as aspects that also influenced the overall fidelity results.

Agreement between direct observations and audio-recordings for assessing the fidelity of delivery was found to be excellent.<sup>40</sup> Agreement between both of these methods and provider self-report assessment was lower, as providers consistently rated themselves higher than the independent raters. These findings are perhaps unsurprising, as both direct observations and audio-recordings were rated by the same researcher, and numerous previous studies have shown that providers' subjective assessments of fidelity are often rated higher than independent assessments.<sup>31,32,41</sup> Taking direct observations as the commonly-cited 'gold standard',<sup>11,18,20</sup> these findings reinforce that self-report methods may not be the most accurate method for assessing fidelity in a complex behaviour change study. However, they may still have their place for recording data and also for enhancing fidelity to the protocol by serving as an aide memoire for providers.<sup>42</sup> Although direct observations and audio-recordings have their own limitations<sup>24,43</sup>, previous piloting of these assessment methods found that they were feasible and acceptable to physiotherapists.<sup>27</sup> Additionally, the good agreement between audio-recordings and direct observations found in this study suggests that audio-recordings may be a viable alternative with limited resources, as has been done in similar interventions.<sup>44</sup> However, where resources allow, a combination of multiple quantitative methods may provide the most in-depth assessment of fidelity.



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3 One of the key study findings of this study was reinforcing the value of using mixed methods  
4 research for the assessment of fidelity. This approach was emphasised in the recent MRC  
5 guidelines for conducting process evaluations of complex interventions<sup>6</sup>, and is becoming  
6 increasingly used in the widespread implementation of evidence-based interventions<sup>45</sup> but  
7 does not yet appear to be common practice within fidelity assessments of behaviour change  
8 interventions.<sup>10,21</sup> The integration of quantitative and qualitative results enabled the  
9 triangulation of findings to provide a better overall picture of the fidelity of the SOLAS  
10 intervention and its influencing factors. The importance of the qualitative contribution to  
11 answering the ‘why’ question is evident in the fact that the physiotherapist interviews  
12 unearthed strong participant and programme-level factors associated with fidelity results that  
13 were not apparent from the quantitative data alone. Whilst this may be predominantly due to  
14 the focus of the quantitative analysis on physiotherapist-level variables which were chosen  
15 based on existing literature, the participant and programme-level factors identified by this  
16 analysis such as group dynamics or amount of programme content may have been difficult to  
17 quantitatively analyse to demonstrate association with fidelity results.  
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30 This study found that the factors that may influence the fidelity of an interventions’ delivery  
31 can occur on three levels – provider, participant and programme. Where previous studies  
32 have explored factors that have influenced fidelity of intervention delivery, many have  
33 focused solely on provider-level factors, demonstrating associations between fidelity and  
34 factors such as provider training or skills.<sup>13,19,21,35</sup> The findings of this study have valuable  
35 implications for future studies that aim to assess and enhance fidelity of similar interventions  
36 as they indicate that planning for fidelity should include considering potential influencing  
37 factors at each of these three levels. These results are consistent with recent conclusions by  
38 Masterson-Algar et al. in a stroke rehabilitation setting<sup>14</sup> who found that investigating  
39 fidelity within clinical trials should also take the individual needs of patients into account,  
40 and also concur with the findings of an education-based intervention that found the most  
41 common reason for adaptation within intervention delivery was insufficient time.<sup>46</sup>  
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51 On the physiotherapist-level, better knowledge of the intervention content and structure was  
52 found to positively correlate with quantitative fidelity scores, with a causative link  
53 established via the qualitative investigation. This echoes previous findings by Huijg et al.  
54 who showed that physiotherapist skill level was one of the most important predictors of  
55 fidelity.<sup>21</sup> A more targeted approach to enhancing fidelity in future interventions may  
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3 therefore be warranted, such as identifying physiotherapists at higher risk of lower fidelity  
4 using post-training evaluation scores and employing more focused fidelity assessment of  
5 delivery or further training for these providers,<sup>13</sup> as has been previously employed in similar  
6 interventions.<sup>10,44</sup> The results of the study also showed that physiotherapists with more  
7 experience of certain aspects tended to emphasise these at the expense of delivering other  
8 components as comprehensively as intended in the protocol. These experience-based  
9 adaptations invoke the well-established issue of adaptation versus fidelity. For years, research  
10 has debated the concept of fidelity versus adaptation, with the case made for both strict  
11 fidelity and for modifying interventions.<sup>47</sup> A third view is that both fidelity and adaptation  
12 are essential, and achieving an appropriate balance between both can allow an intervention to  
13 maximise its effectiveness, while being generalizable and flexible enough to be  
14 implementable.<sup>48,49</sup> To achieve this, our fidelity checklists included components that  
15 encouraged elements of treatment individualisation (e.g. individualised feedback regarding  
16 exercises). However, it may be that these checklists still did not allow for enough  
17 individualisation within delivery, an aspect that should be considered by other researchers  
18 seeking to conduct similar fidelity assessments.  
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31 A limitation of this study was the timing of the interviews, which did not allow a 'pure'  
32 convergent/triangulation design. Typically, the qualitative and quantitative methods occur  
33 concurrently in this design,<sup>28</sup> however, they were scheduled to take place after  
34 physiotherapists had experienced delivery of an entire six-week SOLAS intervention.  
35 Although a sequential explanatory design<sup>30</sup> where quantitative results were analysed prior to  
36 completing the interviews might have enabled further probing of the factors influencing  
37 fidelity, interviews were conducted within two weeks of the intervention completion to  
38 minimise recall bias. Due to time constraints it was not possible to have the quantitative data  
39 collected and analysed beforehand. Finally, this study mostly focuses on the adherence of  
40 delivery (e.g. intervention content and duration) and does not address the *quality* or  
41 competence of delivery of SOLAS (e.g. interpersonal or communication style of the  
42 physiotherapist), or use of specific BCTs, which is being addressed in a separate publication.  
43 This study also does not examine the broader aspects of fidelity such as provider training or  
44 participant receipt, as these were beyond the scope of this publication and will be addressed  
45 in a future paper.  
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## 58 CONCLUSIONS

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3 In process evaluations and fidelity assessments of large scale complex interventions it is often  
4 recommended to complete and report the results of the fidelity assessment before the trial  
5 outcomes so as not to bias reporting.<sup>50</sup> Future work will investigate the relationship between  
6 this evaluation of fidelity of delivery and the SOLAS feasibility trial outcomes (analysis  
7 currently underway), enabling a potentially more insightful and accurate interpretation of  
8 findings. This study also has valuable implications for further research and the overall science  
9 of fidelity as it contributes much-needed information to the limited current evidence for the  
10 application of fidelity assessment methods within the area of complex behaviour change. The  
11 findings have demonstrated how multiple quantitative methods can be used to assess the  
12 fidelity of delivery of a complex behaviour change intervention, and that a combination of  
13 methods may be most suitable, depending on their acceptability and available resources. We  
14 have also shown how the use of a mixed methods approach, integrating both quantitative and  
15 qualitative data, provides a more insightful understanding of the factors influencing fidelity.  
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### **AUTHORS' CONTRIBUTION**

ET conceptualized and designed the study and conducted the data collection and analysis. JM and DAH provided guidance on the design. DAH is the principal investigator of the SOLAS trial and obtained funding for this study within the trial. All authors provided methodological consultation and were involved in substantial contributions to reviewing of the drafts. All authors approved the final version of the manuscript.

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### **CONFLICTS OF INTEREST**

None

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## Supplementary Files

### Supplementary File 1: Quantitative fidelity checklists used

#### INTERVENTION SESSION CHECKLIST (OBSERVATION/AUDIO-RECORDING):

##### Cover sheet (completed for each session)

<b>Date:</b>	
<b>Venue:</b>	
<b>Physiotherapist Name:</b>	
<b>Other staff involved:</b>	Name(s): Role: (e.g. set-up/delivery/support)
<b>Session number (tick):</b>	1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/>
<b>Start time (class):</b>	
<b>Finish time (class):</b>	
<b>Time spent on education (mins):</b>	
<b>Time spent on exercise (mins):</b>	
<b>Method of Observation:</b>	In-vivo/Audio-recording
<b>Adverse event(s)/issue(s) (circle):</b>	If yes give brief details:
Y/N	



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<b>Deviations from protocol/proscribed components delivered?</b>	Yes/No Details:			
<b>General notes on fidelity of session:</b>				
<b>INTERVENTION COMPONENT CHECKLIST:</b>	<b>YES (2)</b>	<b>NO (0)</b>	<b>ATTEMPTED (1)</b>	<b>N/A</b>
<b>Session 1:</b>				
<b>Materials</b>				
<b>Intervention folder</b> given to participants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Use of <b>participant intervention folder</b> actively facilitated <b>throughout</b> session	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Name stickers/badges</b> given to participants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Pens offered/provided</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Powerpoint slides</b> used	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Introduction</b>				
<b>Introductions/welcome</b> made	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Set <b>clear expectations</b> - aims, content and structure of programme addressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Rationale</b> for weekly attendance provided	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Education</b>				

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Rationale for self-management provided	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Posture addressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Cycle of change addressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Disease characteristics, prevalence and causes of OA/CLBP addressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Recommended activity levels/benefits of exercise addressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Individual reflection on activity/recommendations facilitated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Goal setting introduced	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Action planning introduced	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Attention drawn to Action Plan sheets within intervention folder, encouraged use	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Attention drawn to Activity Diaries within intervention folder, encouraged use	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Participants given a chance/encouraged to contribute to discussion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Exercise</b>				
Room set up for exercise (equipment, sheets)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Protocol exercises demonstrated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Attention drawn to Exercise Programme Diary within intervention folder, encouraged use	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Rationale for exercises provided	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Participants given a chance to attempt and practice protocol exercises	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Individual feedback provided	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Review and Planning</b>				
Session review - activity levels and goal setting recap	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Proscribed components delivered?	<input type="checkbox"/> (-2)	<input type="checkbox"/>		
Total score (Yes = 2, Attempted = 1, No =0)				
Overall Adherence score				
<b>Session 2:</b>				
<b>INTERVENTION COMPONENT CHECKLIST:</b>	<b>YES (2)</b>	<b>NO (0)</b>	<b>ATTEMPTED (1)</b>	<b>N/A</b>

<b>Materials</b>				
Use of <b>participant intervention folder</b> actively facilitated throughout session	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Name stickers/badges</b> given to participants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Pens offered/provided</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Pedometers</b> offered	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Powerpoint slides</b> used	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Recap and Review</b>				
<b>Welcome back</b> made	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Review</b> of previous week activities/action plans	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Education</b>				
<b>Set clear expectations – content of session</b> outlined	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Activity-rest cycle</b> and <b>pacing</b> explained	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Individual reflection</b> on <b>current pacing/activity-rest</b> facilitated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Factors influencing pain</b> addressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Goal setting</b> facilitated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Action planning</b> facilitated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Action Plan sheets</b> use encouraged/facilitated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Attention drawn to <b>Walking/Activity Diary</b> within intervention folder, encouraged use	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Participants given a chance/encouraged to <b>contribute to discussion</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Exercise</b>				
<b>Room set up</b> for exercise (equipment, sheets)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Protocol exercises demonstrated</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Exercise Programme Diary</b> use encouraged	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Rationale</b> for exercises provided	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Participants given a chance to <b>attempt and practice protocol</b> exercises	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Individual feedback</b> provided	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Session Planning and Review</b>				
Session review - <b>goal setting and action planning recap</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Proscribed components delivered?</b>	<input type="checkbox"/> (-2)	<input type="checkbox"/>		
Total score (Yes = 2, Attempted = 1, No =0)				

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Overall Adherence score				
<b>Session 3:</b>				
<b>INTERVENTION COMPONENT CHECKLIST:</b>	<b>YES (2)</b>	<b>NO (0)</b>	<b>ATTEMPTED (1)</b>	<b>N/A</b>
<b>Materials</b>				
Use of <b>participant intervention folder</b> actively facilitated <b>throughout</b> session	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Tape measures</b> offered	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Pens offered/provided</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Powerpoint slides</b> used	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Recap and Review</b>				
Previous week <b>Activity Action Plan</b> reviewed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Problem-solving</b> of previous week <b>Activity Action Plan</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Action Plan sheets</b> use encouraged/facilitated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Education</b>				
<b>Set clear expectations – content of session</b> outlined	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Obesity and effect on pain</b> addressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Balance between weight/activity</b> addressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Individual reflection</b> on <b>weight/activity</b> balance facilitated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Skills for maintaining healthy weight</b> addressed (e.g. waist measurement, food diary)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Attention drawn to <b>Healthy Eating Booklet</b> within intervention folder, <b>encouraged use</b>				
Attention drawn to <b>Walking/ Activity Diary</b> within intervention folder, <b>encouraged use</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Attention drawn to <b>Food &amp; Exercise Diary</b> within intervention folder, <b>encouraged use</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Participants given a chance/encouraged to <b>contribute to discussion</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Exercise</b>				
<b>Room set up</b> for exercise (equipment, sheets)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Protocol exercises demonstrated</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Exercise Programme Diary use encouraged	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Rationale for exercises provided	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Participants given a chance to attempt and practice protocol exercises	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Individual feedback provided	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Session Planning and Review</b>				
Session review - goal setting and action planning recap integrating food and exercise diary	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Proscribed components delivered?	<input type="checkbox"/> (-2)	<input type="checkbox"/>		
Total score (Yes = 2, Attempted = 1, No =0)				
Overall Adherence score				
<b>Session 4:</b>				
<b>INTERVENTION COMPONENT CHECKLIST:</b>				
	<b>YES (2)</b>	<b>NO (0)</b>	<b>ATTEMPTED (1)</b>	<b>N/A</b>
<b>Materials</b>				
Use of participant intervention folder actively facilitated throughout session	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Pens offered/provided	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Powerpoint slides used	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Midway Recap and Review</b>				
Previous week Activity Action Plan reviewed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Problem-solving of previous week Activity Action Plan	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Action Plan sheets use encouraged/facilitated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Walking/ Activity Diary use encouraged	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Education</b>				
Set clear expectations – content of session outlined	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Rationale for using pain relief given (e.g. pain pathway explained)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Methods of pain relief addressed (e.g. medication, heat/ice, TENS/acupuncture)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Individual reflection on use of pain relief facilitated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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Participants given a chance/encouraged to <b>contribute to discussion</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Exercise</b>				
<b>Room set up</b> for exercise (equipment, sheets)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Protocol exercises demonstrated</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Exercise Programme Diary</b> use encouraged	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Rationale for exercises</b> provided	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Participants given a chance to <b>attempt and practice protocol</b> exercises	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Individual feedback</b> provided	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Session Planning and Review</b>				
Session review - <b>goal setting and action planning</b> recap	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Proscribed components delivered?</b>	<input type="checkbox"/> (-2)	<input type="checkbox"/>		
Total score (Yes = 2, Attempted = 1, No =0)				
Overall Adherence score				
<b>Session 5:</b>				
<b>INTERVENTION COMPONENT CHECKLIST:</b>				
	<b>YES (2)</b>	<b>NO (0)</b>	<b>ATTEMPTED (1)</b>	<b>N/A</b>
<b>Materials</b>				
Use of <b>participant intervention folder</b> actively facilitated <b>throughout</b> session	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Pens offered/provided</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Relaxation CD</b> offered	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Powerpoint slides</b> used	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Recap and Review</b>				
Previous week <b>Activity Action Plan</b> reviewed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Problem-solving</b> of previous week <b>Activity Action Plan</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Action Plan sheets</b> use encouraged/facilitated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Walking/ Activity Diary</b> use encouraged	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Education</b>				
<b>Set clear expectations – content of session</b> outlined	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Recognising and managing flare-ups addressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Individual reflection about flare-ups facilitated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Effect of mood on pain addressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Participants given a chance/encouraged to contribute to discussion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Exercise</b>				
Room set up for exercise (equipment, sheets)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Protocol exercises demonstrated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Exercise Programme Diary use encouraged	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Rationale for exercises provided	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Participants given a chance to attempt and practice protocol exercises	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Individual feedback provided	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Relaxation Session</b>				
Relaxation techniques explained and practiced	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Session Planning and Review</b>				
Session review - goal setting and action planning recap with integration of relaxation techniques	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Proscribed components delivered?	<input type="checkbox"/> (-2)	<input type="checkbox"/>		
Total score (Yes = 2, Attempted = 1, No =0)				
Overall Adherence score				
<b>Session 6:</b>				
<b>INTERVENTION COMPONENT CHECKLIST:</b>				
	<b>YES (2)</b>	<b>NO (0)</b>	<b>ATTEMPTED (1)</b>	<b>N/A</b>
<b>Materials</b>				
Use of participant intervention folder actively facilitated throughout session	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Pens offered/provided	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Handouts on local resources and supports provided	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Powerpoint slides used	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Recap and Review</b>				
Previous week Activity Action Plan reviewed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Problem-solving of previous week Activity Action Plan	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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<b>Action Plan sheets</b> use encouraged/facilitated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Walking/ Activity Diary</b> use encouraged	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Education</b>				
<b>Set clear expectations – content of session</b> outlined	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Core skills of programme</b> reviewed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Aims of long-term self-management</b> addressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Local resources and supports</b> discussed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Participants given a chance/encouraged to <b>contribute to discussion</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Exercise</b>				
<b>Room set up</b> for exercise (equipment, sheets)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Protocol exercises demonstrated</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Exercise Programme Diary</b> use encouraged	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Rationale for exercises</b> provided	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Participants given a chance to <b>attempt and practice protocol</b> exercises	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Individual feedback</b> provided	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Session Planning and Review</b>				
Session review – <b>long term goal setting and action planning</b> recap	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Activity diaries <b>use recorded</b> (if willing)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Proscribed components delivered?</b>	<input type="checkbox"/> (-2)	<input type="checkbox"/>		
Total score (Yes = 2, Attempted = 1, No =0)				
Overall Adherence score				

**Yes** = Fully addressed by the Physiotherapist – could not do more

**Attempted** = Reasonable attempt made to address this – could do more

**No** = No attempt made to address this



**INTERVENTION SESSION CHECKLIST (SELF-REPORT)**

Self-report checklists covered similar components to observation and audio as provided above - different cover sheet (completed for each session) provided below

<b>PCCC Site:</b>	<b>Date:</b>	<b>Class: circle</b> 1 2 3 4 5 6	<b>Physiotherapist Name:</b>
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**PERSONNEL**

<b>Other staff involved in setting up class:</b>	Yes <input type="checkbox"/> No <input type="checkbox"/>	<b>Names/Staff Grade:</b>
<b>Other staff involved in providing class:</b>	Yes <input type="checkbox"/> No <input type="checkbox"/>	<b>Names/Staff Grade:</b>

**ATTENDANCE**

	<b>Present</b>	<b>Absent</b>
<b>Number of Clients:</b>		
<b>Names of non-attenders:</b>	<b>Reasons for non-attendance [if known]</b>	
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**CLASS PREPARATION**

<b>Time to review materials [mins]:</b>	<b>Time to set up class [mins]:</b>	<b>Time to take down class [mins]:</b>
<b>Start Time:</b>	<b>End Time:</b>	<b>Comments:</b>

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**CLASS DELIVERY**

	<b>Education</b>	<b>Exercise</b>
<b>Time to deliver [mins]:</b>		
<b>Comments:</b>		
<b>Deviations from protocol: Content/time</b>	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>If 'yes' give details and reason[s]</b>		

**TREATMENT-RELATED EVENT – any unforeseen event/issue should be reported to Deirdre Hurley**

<b>During class:</b> Yes <input type="checkbox"/> No <input type="checkbox"/>	<b>After class:</b> Yes <input type="checkbox"/> No <input type="checkbox"/>	<b>Reported to Deirdre:</b> Yes <input type="checkbox"/> No <input type="checkbox"/>
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When patient is discharged please give this completed form to UCD Research Physiotherapist or scan and email to [physiostudy@ucd.ie](mailto:physiostudy@ucd.ie)

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Supplementary File 2: Physiotherapist baseline characteristics										
	Wave 1				Wave 2					
Physiotherapy Site	A	B	C	D	A	B	C	E	F	G
Physiotherapist	A1	B1	C1	D1	A1	B2	C2	E1	F1	G1
Gender	F	F	F	M	F	F	F	F	F	F
Experience (years qualified)	5	25	8	12	5	25	10	6	19	11
Group experience (years delivering group physiotherapy)	1	3	8	2	1	10	3	1	15	7
Post-training evaluation score (%)	74%	81.5%	90.5%	83.4%	74%	88.5%	81.8%	88.2%	78.1%	94.4%
Previous training in similar interventions (Y/N)	N	Y	Y	Y	N	Y	Y	Y	Y	Y
F= female, M=male, Y=yes, N=no										

## Supplementary File 3: Physiotherapist interviews topic guide

### SOLAS Programme Semi-Structured Interviews with Physiotherapists

#### Interview Schedule

**Ice-breaker** – describe your experience in running group-based programmes for these or other populations before this study. How many weeks of the SOLAS programme did you deliver?

#### Therapist Views on Experience of Delivering the Programme

- What are your overall impressions of the programme having delivered it for first/second time?
  - Content overall and week by week – education and exercise components – time for each- managing group dynamics – mixed ability/diagnosis and ages of clients
- What aspects did you find easy/challenging to deliver?  
[content/communication/behaviour change/goal setting/action planning – these were emphasised in training]
- Views on feasibility of class size of up to 8 clients with one physiotherapist to deliver?  
[none delivered a class of this size – their views on running small numbers v the target of 8]
- How well do you feel you delivered the programme as intended from the training received?
  - Following the slide content/script – was it difficult/did you want to edit - which parts?
  - Content/needs supportive delivery style/ behaviour change techniques
  - Views on giving advice/setting goals with patients and following through and being needs supportive (using SDT) e.g. using non-controlling language, enabling patient input and choice; providing positive and personalised feedback to patients?
  - Difficult/constrained by research?
- For the aspects not delivered as planned from training give reasons –
  - prompt on potential barriers to delivery [the availability of resources (e.g. staffing, suitable venue, administrative staff, time constraints); appropriate patient selection and screening, patient uptake and engagement with programme and the potential need to individualise treatment within group]
- How much additional work did delivering the programme and participating in this study place upon you? [Specify – preparation time – reading the manual and supplementary materials, setting up the venue, time to deliver – on top of other work, completion of treatment record forms after each class, completion of post training questionnaires]?
  - Is this acceptable? What modifications would you suggest for future waves?
- What are your impressions of the resources provided to you to support delivery of the programme? [Training Manual /Intervention Manual/Intervention Slides/SOLAS poster]
  - How much have you used them? What was useful/not useful in terms of helping you deliver the programme as intended?
  - Views on continuing to use powerpoint versus flip chart or handouts only?
  - Suggestions for modifications for future waves
- What are your impressions of the venue in terms of its suitability for delivering the programme? [Prompt – accessibility, space, equipment for delivering education and exercise component number of stations, sound quality to allow communication to the

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3 group/individuals during exercises  
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6 **Views on sustainability of the Programme**

- 7 • What is your opinion of the feasibility of delivering the programme in the future within  
8 the study/within normal practice?  
9 • Would you deliver the programme outside the study?  
10 • How would you deliver it? What materials would you use? What would you leave out?  
11 Who would you deliver it to?  
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14 **Views on Research Elements of the Programme**

- 15 • Views on research elements of the programme [pre and post training questionnaires,  
16 direct observation during classes, audio recordings, treatment record forms]  
17 ○ Intrusiveness/time/feasibility Any suggestions for modifications for future waves  
18 • Views on level and modes of communication with the research team throughout the  
19 study from training to completion of this wave  
20 ○ Suggestions for modifications for future waves  
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peer review only

<b>Supplementary File 4: Agreement between assessment methods</b>				
	Direct Observation v Self-Report (n=24)	Direct Observation v Audio- Recordings (n=24)	Audio-Recordings v Self-Report (n=60)	Audio-Recordings Rater 1 v Rater 2 (Inter-rater reliability) (n=12)
<b>Overall agreement</b>	74.6%	86.6%	75.4%	84.6%
<b>% Agreement per category:</b>				
<b>Materials</b>	74.5%	82.67%	70.1%	84.6%
<b>Introduction and Review</b>	65.3%	86.5%	57%	81.6%
<b>Education</b>	84.6%	90.3%	87.3%	76.7%
<b>Exercise</b>	70.8%	86%	78%	83.3%
<b>Review and Planning</b>	50%	76.2%	46%	100%

# BMJ Open

## Using mixed methods to assess fidelity of delivery and its influencing factors in a complex self-management intervention for people with osteoarthritis and low back pain

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Manuscript ID	bmjopen-2016-015452.R2
Article Type:	Research
Date Submitted by the Author:	31-Mar-2017
Complete List of Authors:	Toomey, Elaine; National University of Ireland - Galway, School of Psychology Matthews, James; University College Dublin, Hurley, Deirdre; University College Dublin, Physiotherapy and Performance Science
<b>Primary Subject Heading</b>:	Sports and exercise medicine
Secondary Subject Heading:	Sports and exercise medicine, Rheumatology, Qualitative research, Patient-centred medicine
Keywords:	implementation fidelity, PRIMARY CARE, complex interventions, behaviour change

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Manuscripts

**Title**

Using mixed methods to assess fidelity of delivery and its influencing factors in a complex self-management intervention for people with osteoarthritis and low back pain

**Authors**

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**Word count**

4229



**ABSTRACT:**

**Objectives and design:** Despite an increasing awareness of the importance of fidelity of delivery within complex behaviour change interventions, it is often poorly assessed. This mixed methods study aimed to establish the fidelity of delivery of a complex self-management intervention and explore the reasons for these findings using a convergent/triangulation design.

**Setting:** Feasibility trial of the Self-management of Osteoarthritis and Low back pain through Activity and Skills (SOLAS) intervention, delivered in primary care physiotherapy.

**Methods and outcomes:** 60 SOLAS sessions were delivered across seven sites by nine physiotherapists. Fidelity of delivery of pre-specified intervention components was evaluated using 1) audio-recordings (n=60), direct-observations (n=24) and self-report checklists (n=60) and 2) individual interviews with physiotherapists (n=9). Quantitatively, fidelity scores were calculated using percentage means and standard deviations of components delivered. Associations between fidelity scores and physiotherapist variables were analysed using Spearman's correlations. Interviews were analysed using thematic analysis to explore potential reasons for fidelity scores. Integration of quantitative and qualitative data occurred at an interpretation level using triangulation.

**Results:** Quantitatively, fidelity scores were high for all assessment methods; with self-report (92.7%) consistently higher than direct-observations (82.7%), or audio-recordings (81.7%). There was significant variation between physiotherapists' individual scores (69.8% - 100%). Both qualitative and quantitative data (from physiotherapist variables) found that physiotherapists' knowledge (Spearman's association at  $p=0.003$ ) and previous experience ( $p=0.008$ ) were factors that influenced their fidelity. The qualitative data also postulated participant-level (e.g. individual needs) and programme-level factors (e.g. resources) as additional elements that influenced fidelity.

**Conclusion:** The intervention was delivered with high fidelity. This study contributes to the limited evidence regarding fidelity assessment methods within complex behaviour change interventions. The findings suggest a combination of quantitative methods is suitable for the

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3 assessment of fidelity of delivery. A mixed methods approach provided a more insightful  
4 understanding of fidelity and its influencing factors.  
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### 8 **Article summary – strengths and limitations**

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- 10 • This mixed methods investigation of fidelity of delivery and its influencing factors  
11 provides valuable information on fidelity assessment methods and factors to be  
12 considered in developing and evaluating complex behaviour change interventions
  - 13 • The novel use of mixed methods to assess fidelity in this study enabled increased  
14 certainty in findings where qualitative data corroborated the quantitative results
  - 15 • This study does not explore the fidelity of the *quality* of delivery (e.g. therapist  
16 competence) or specific behaviour change techniques (BCTs) which will be reported in a  
17 separate publication  
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# USING MIXED METHODS TO ASSESS FIDELITY OF DELIVERY AND ITS INFLUENCING FACTORS IN A COMPLEX SELF- MANAGEMENT INTERVENTION

## INTRODUCTION

Fidelity of delivery is an important, yet often overlooked aspect of behaviour change interventions and has been defined as the degree to which an intervention, treatment or program is delivered as intended by the intervention developers.<sup>1,2</sup> Without adequately addressing fidelity in behaviour change research, it is uncertain that changes observed in study outcomes are due to the influence of the independent variable (the intervention being investigated) and not due to variability in its implementation, e.g. extraneous elements that may have been added (either accidentally or purposely), or essential elements of the intervention that were omitted.<sup>3</sup> In particular, as behaviour change interventions are often complex interventions that typically involve several components with the potential to affect or influence outcomes separately, it is especially important to incorporate adequate fidelity planning and assessment into the development of interventions of this nature.<sup>4</sup>

Despite a recent increased emphasis on improved assessment and reporting of what happens within complex behaviour change interventions,<sup>5,6</sup> fidelity is still poorly addressed within this context, with few examples of fidelity being assessed comprehensively or reported adequately.<sup>7-9</sup> Where studies have assessed fidelity within a behaviour change healthcare context, there is often limited exploration of the factors that might have influenced that fidelity.<sup>10,11</sup> Previous work that *has* specifically examined influencing factors in areas of public health, obesity and stroke research found that provider-level variables, such as experience, knowledge or skills, may influence fidelity of delivery.<sup>12-15</sup> Although the use of both quantitative and qualitative methods has been previously recommended to comprehensively assess fidelity,<sup>16-18</sup> this guidance is not consistently followed. Consequently, the use of quantitative methods in isolation may not allow for exploration of the factors influencing fidelity, knowledge of which could improve how fidelity is enhanced and assessed in future similar interventions.<sup>19</sup> For example, French et al.<sup>11</sup> used audio-recordings and self-report methods to assess the fidelity of delivery of an educational

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3 intervention for general practitioners. The authors acknowledged that the quantitative study  
4 design did not allow them to explore the reasons for variations in fidelity scores found.  
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8 According to existing guidelines for addressing fidelity within behaviour change research  
9 developed by the National Institutes of Health Behaviour Change Consortium (NIHBCC),<sup>18</sup>  
10<sup>,20</sup> the fidelity of delivery of the intervention by providers is one particularly important aspect  
11 of fidelity. This aspect considers strategies that enhance the fidelity of delivery (e.g. using  
12 treatment manuals or intervention protocols) and methods that assess this delivery (e.g.  
13 provider self-report, audio or video-recorded observations and direct *in vivo* observations).  
14 However, although previous research has advocated a combination of these strategies in order  
15 to assess fidelity in-depth,<sup>21,22</sup> limited examples exist within the literature. Additionally, few  
16 studies have explored the relationship between these methods, and the accuracy of potentially  
17 more feasible methods against the ‘gold standard’ of direct observations using pre-specified  
18 criteria<sup>23</sup> has been poorly investigated.<sup>18,19,24</sup> As a result, there is little evidence to justify  
19 the selection of one method over another, or to inform the use of multiple methods  
20 simultaneously.  
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31 The current study is set within the context of the SOLAS (Self-Management of Osteoarthritis  
32 and Low back pain through Activities and Skills) feasibility trial [ISRCTN49875385].<sup>25</sup> The  
33 trial aims to evaluate the feasibility of providing the SOLAS intervention (experimental  
34 group) to promote self-management for patients with osteoarthritis (OA) of the hip/ knee  
35 and/or chronic low back pain (CLBP) compared to usual physiotherapy, which will serve as  
36 the pragmatic control group in order to determine the feasibility of moving to a full scale trial  
37 by following the MRC guidelines. The intervention consists of six weekly sessions of 90  
38 minutes to be delivered by a primary care physiotherapist to a group of six to eight people.  
39 Each session is divided into education and exercise sections (each approximately 45 minutes  
40 in duration). During the exercise section, participants are provided with an opportunity to  
41 attempt and practice pre-specified exercises, while the education section is further split into  
42 four categories: Materials - participants are provided with materials intended to supplement  
43 and enhance understanding and uptake of skills; Introduction and Review - at the start of each  
44 session the physiotherapist introduces session aims and reviews goals and action plans with  
45 participants; Education - the physiotherapist facilitates a group discussion on targeted self-  
46 management skill or behaviour of the session using Powerpoint slides and projector; Review  
47 and Planning - before the session concludes, the physiotherapist recaps participants’ planned  
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3 activity levels and action plans. For each category, a number of components (i.e. specific  
4 elements or activities which varied according to the session) were intended to be delivered or  
5 addressed during the session by the physiotherapist (e.g. provision of pedometers, provision  
6 of information on balanced weight and healthy eating), as detailed in an intervention manual  
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activity levels and action plans. For each category, a number of components (i.e. specific elements or activities which varied according to the session) were intended to be delivered or addressed during the session by the physiotherapist (e.g. provision of pedometers, provision of information on balanced weight and healthy eating), as detailed in an intervention manual<sup>25,26</sup> (summarised in Table 1). Prior to participation, physiotherapists were provided with the manual during a two-day training course where background variables were collected, in addition to a post-training assessment.<sup>26</sup> Details of the development and testing of the fidelity protocol used in this study are described elsewhere.<sup>27</sup> This study also does not explore the fidelity of the *quality* of delivery (e.g. therapist competence) or specific behaviour change techniques (BCTs) which will be reported elsewhere.

The aim of this study was to establish the fidelity of delivery of a complex behaviour change intervention and the reasons for these findings using a mixed methods approach. Specifically, the study objectives were:

- 1) To evaluate the agreement of multiple methods for assessing fidelity of delivery
- 2) To establish the fidelity of delivery of the SOLAS complex behaviour change intervention
- 3) To explore the potential factors that may have influenced these fidelity results

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<b>Session number</b>	<b>Self-management behaviours/skills targeted</b>	<b>Session section (intended duration)</b>	<b>Session category and component example*</b>
<b>1</b>	<ul style="list-style-type: none"> <li>• Physical activity</li> <li>• Goal-setting</li> </ul>	Education (45 mins)	<ul style="list-style-type: none"> <li>• Materials               <ul style="list-style-type: none"> <li>○ <i>Provide participant handbook</i></li> </ul> </li> <li>• Introduction and Review               <ul style="list-style-type: none"> <li>○ <i>Introduce programme aims</i></li> </ul> </li> <li>• Education               <ul style="list-style-type: none"> <li>○ <i>Provide information on benefits of exercise/physical activity</i></li> </ul> </li> <li>• Review and Planning               <ul style="list-style-type: none"> <li>○ <i>Review of SOLAS programme and activity levels</i></li> </ul> </li> </ul>
		Exercise (45 mins)	<ul style="list-style-type: none"> <li>• Exercise               <ul style="list-style-type: none"> <li>○ <i>Demonstrate protocol exercises</i></li> </ul> </li> </ul>
<b>2</b>	<ul style="list-style-type: none"> <li>• Pacing (balancing activity/rest)</li> <li>• Physical activity</li> <li>• Goal-setting</li> </ul>	Education (45 mins)	<ul style="list-style-type: none"> <li>• Materials               <ul style="list-style-type: none"> <li>○ <i>Offer pedometers</i></li> </ul> </li> <li>• Introduction and Review               <ul style="list-style-type: none"> <li>○ <i>Review of previous week activities</i></li> </ul> </li> <li>• Education               <ul style="list-style-type: none"> <li>○ <i>Provide information on activity-rest cycle and pacing</i></li> </ul> </li> <li>• Review and Planning               <ul style="list-style-type: none"> <li>○ <i>Review of session and goal-setting</i></li> </ul> </li> </ul>

		Exercise (45 mins)	<ul style="list-style-type: none"> <li>• Exercise                             <ul style="list-style-type: none"> <li>○ <i>Provide opportunity for participants to practice exercises</i></li> </ul> </li> </ul>
3	<ul style="list-style-type: none"> <li>• Balanced weight/healthy diet</li> <li>• Physical activity</li> <li>• Goal-setting</li> </ul>	Education (45 mins)	<ul style="list-style-type: none"> <li>• Materials                             <ul style="list-style-type: none"> <li>○ <i>Offer tape measures</i></li> </ul> </li> <li>• Introduction and Review                             <ul style="list-style-type: none"> <li>○ <i>Review of previous session action plan</i></li> </ul> </li> <li>• Education                             <ul style="list-style-type: none"> <li>○ <i>Provide information on balanced weight and healthy eating</i></li> </ul> </li> <li>• Review and Planning                             <ul style="list-style-type: none"> <li>○ <i>Review of session and goal-setting</i></li> </ul> </li> </ul>
		Exercise (45 mins)	<ul style="list-style-type: none"> <li>• Exercise                             <ul style="list-style-type: none"> <li>○ <i>Provide opportunity for participants to practice exercises</i></li> </ul> </li> </ul>
4	<ul style="list-style-type: none"> <li>• Managing pain with pain relief</li> <li>• Physical activity</li> <li>• Goal-setting</li> </ul>	Education (45 mins)	<ul style="list-style-type: none"> <li>• Materials                             <ul style="list-style-type: none"> <li>○ N/a</li> </ul> </li> <li>• Introduction and Review                             <ul style="list-style-type: none"> <li>○ <i>Mid-way review</i></li> </ul> </li> <li>• Education                             <ul style="list-style-type: none"> <li>○ <i>Provide information on pain management with ice/heat</i></li> </ul> </li> <li>• Review and Planning                             <ul style="list-style-type: none"> <li>○ <i>Review of session and goal-setting</i></li> </ul> </li> </ul>
		Exercise (45 mins)	<ul style="list-style-type: none"> <li>• Exercise</li> </ul>

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			<ul style="list-style-type: none"> <li>○ <i>Provide opportunity for participants to practice exercises</i></li> </ul>
5	<ul style="list-style-type: none"> <li>• Managing mood (with relaxation)</li> <li>• Physical activity</li> <li>• Goal-setting</li> </ul>	Education (45 mins)	<ul style="list-style-type: none"> <li>• Materials               <ul style="list-style-type: none"> <li>○ <i>Offer relaxation CD</i></li> </ul> </li> <li>• Introduction and Review               <ul style="list-style-type: none"> <li>○ <i>Review of previous session action plan</i></li> </ul> </li> <li>• Education               <ul style="list-style-type: none"> <li>○ <i>Provide information on recognising and managing flare-ups</i></li> </ul> </li> <li>• Review and Planning               <ul style="list-style-type: none"> <li>○ <i>Review of session and goal-setting</i></li> </ul> </li> </ul>
		Exercise (45 mins)	<ul style="list-style-type: none"> <li>• Exercise               <ul style="list-style-type: none"> <li>○ <i>Provide opportunity for participants to practice exercises</i></li> </ul> </li> </ul>
6	<ul style="list-style-type: none"> <li>• Long-term management</li> <li>• Physical activity</li> <li>• Goal-setting</li> </ul>	Education (45 mins)	<ul style="list-style-type: none"> <li>• Materials               <ul style="list-style-type: none"> <li>○ <i>Offer 'local resources to support physical activity' leaflet</i></li> </ul> </li> <li>• Introduction and Review               <ul style="list-style-type: none"> <li>○ <i>Review of previous session action plan</i></li> </ul> </li> <li>• Education               <ul style="list-style-type: none"> <li>○ <i>Provide information on local resources and supports</i></li> </ul> </li> <li>• Review and Planning               <ul style="list-style-type: none"> <li>○ <i>Long-term goal setting and action planning</i></li> </ul> </li> </ul>
		Exercise (45 mins)	<ul style="list-style-type: none"> <li>• Exercise               <ul style="list-style-type: none"> <li>○ <i>Provide opportunity for participants to practice exercises</i></li> </ul> </li> </ul>



<b>Samples involved</b>											
	<b>Wave 1</b>				<b>Wave 2</b>						<b>Total n=</b>
Physiotherapy Site code	A	B	C	D	A	B	C	E	F	G	<b>10 (7)**</b>
Physiotherapist code	A1	B1	C1	D1	A1	B2	C2	E1	F1	G1	<b>9***</b>
Number of participants recruited	4	6	4	2	4	4	5	4	7	5	<b>45</b>
Sessions delivered	6	6	6	6	6	6	6	6	6	6	<b>60</b>
Direct Observations	3	3	3	3	2	2	3	2	1	2	<b>24 (40%)</b>
Self-Report	6	6	6	6	6	6	6	6	6	6	<b>60 (100%)</b>
Audio-Recordings (rater 1)	6	6	6	6	6	6	6	6	6	6	<b>60 (100%)</b>
Audio-Recordings (rater 2)	3	3	3	3	0	0	0	0	0	0	<b>12 (20%)</b>
<p>*A complete list of category components is provided in the Supplementary Files</p> <p>**Seven sites were involved in total, but three of these delivered the intervention in both waves</p> <p>***One physiotherapist delivered the intervention in both waves</p>											

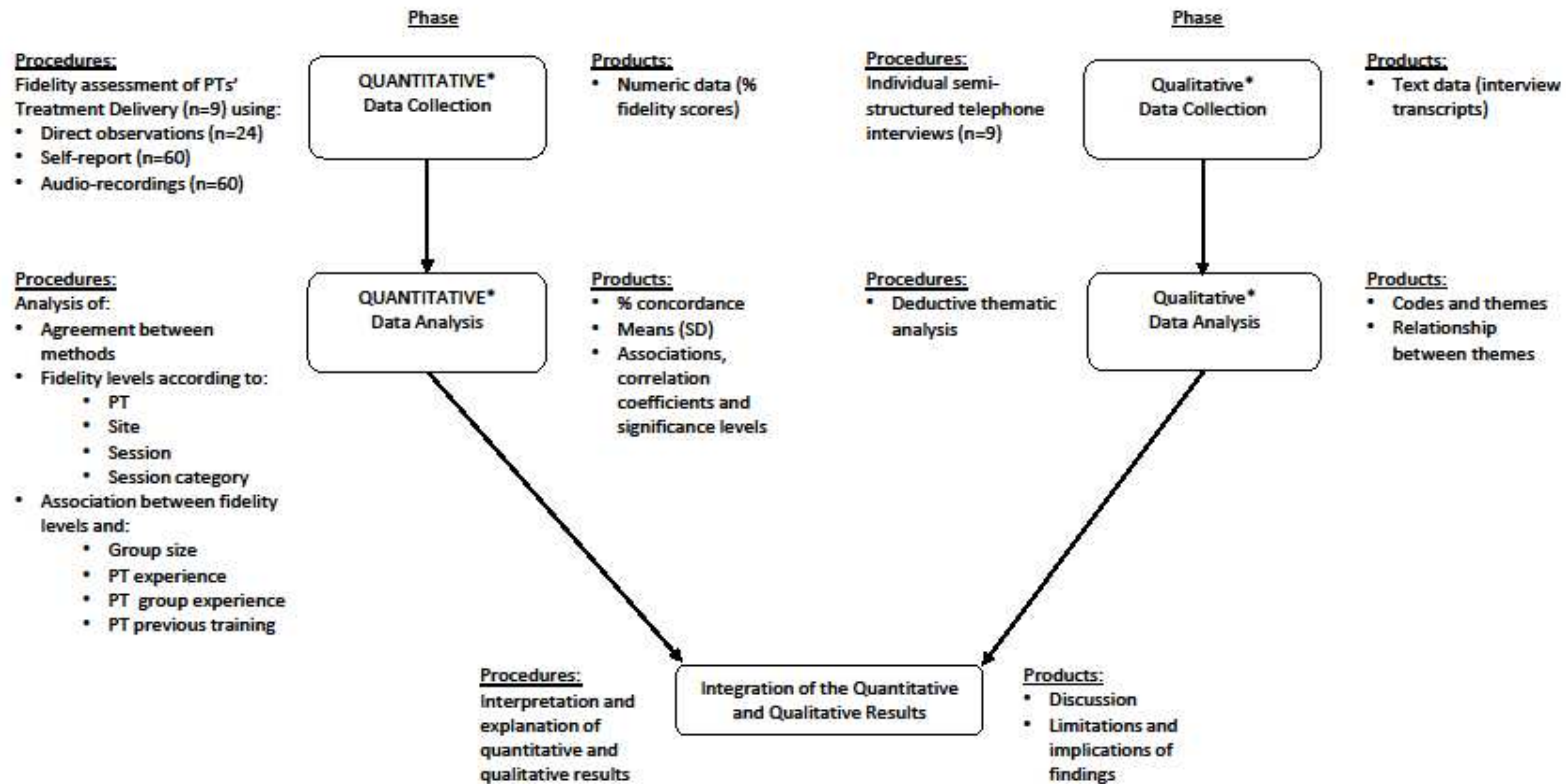
## METHODS

### Ethics

Ethical approval for this study was granted by University College Dublin's Human Research Ethics Committee (LS-13-54). Written informed consent was obtained from all physiotherapists and participants prior to any observations or interviews.

### Design

This observational study was a convergent/triangulation mixed methods design.<sup>28</sup> This mixed methods approach was chosen as it was felt that thorough integration of findings from both quantitative and qualitative methods would achieve a more comprehensive answer to the study questions by enabling the methods to be 'greater than just the sum of their parts'.<sup>29</sup> Figure 1 graphically illustrates the study design, outlining the sequence of research activities, the priority of the methods and the stage at which integration occurred.<sup>30</sup>



\*capitalisation represents weighting or priority, PT = physiotherapist, SD = standard deviation

Figure 1: Diagrammatic representation of mixed methods convergent/triangulation design

## Quantitative phase

### Study sample and procedure:

Data were collected during two of the three waves of the SOLAS feasibility trial (Table 1), representing 71% of the overall trial data. Fidelity of delivery in this study refers to the assessment of both the delivery of session content, i.e. providers deliver the session categories and components as intended (summarised in Table 1) (fidelity of content) and session duration, i.e. providers deliver the session as long as intended (fidelity of duration). Following pilot testing, it was decided to conduct 24 (40% of sessions) randomly selected direct observations (rated by ET), 60 (100%) self-report (rated by the physiotherapists) and 60 (100%) audio-recordings (rated by ET) to assess fidelity of delivery using a-priori checklists (Supplementary File 1) that had been previously found to be feasible for use.<sup>27</sup> To assess inter-rater reliability, 12 sessions (20%) were rated by a second independent rater (AK).<sup>10</sup> Checklists consisted of approximately 25 components for each session, structured according to the SOLAS categories as detailed in Table 1. Components for each session were chosen to address each element specified in the SOLAS intervention manual (summarised in Table 1)<sup>25,26</sup> to be delivered during that session. Each component was rated as 'Yes/Present' equating to a score of two points, 'No/Absent' (zero points), or 'Attempted' (one point). Session duration was documented by all methods, and attendance was recorded by self-report.

### Data analysis:

Fidelity data analysis was consistent with standard procedures<sup>19,31,32</sup> using SPSS v20. Specifically, levels of agreement between methods and inter-rater reliability of audio-recorded data were assessed using percentage concordance. Overall mean fidelity of content scores (i.e. percentage of manual-specified components delivered as intended) and fidelity scores according to physiotherapy site, physiotherapist, session and session category were obtained by calculating total actual scores as a percentage of the total possible score. Means data were compared using ANOVAs and Kruskal-Wallis tests. Fidelity of duration was established by calculating the difference between the actual and the intended session duration using a one-sample Wilcoxon test. Levels of fidelity were interpreted as previously reported in the literature, with 80-100% adherence interpreted as 'high' fidelity, 51-79% as 'moderate' and 0-50% as 'low' fidelity.<sup>3,33,34</sup> Finally, the relationship between fidelity scores and 1) the number of participants present (group size) and 2) physiotherapist variables, i.e. experience (years qualified), group experience (years delivering group physiotherapy), knowledge of

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3 intervention (post-training evaluation score) and previous relevant training (Supplementary  
4 File 2), were calculated using Spearman's correlation coefficient and Mann-Whitney U test.  
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6 These physiotherapist variables were chosen for reasons described in the introduction.  
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### 9 10 **Qualitative phase**

11 The aim of the qualitative phase was to explore physiotherapists' opinions of fidelity of  
12 intervention delivery and the factors that they felt may have influenced their fidelity.  
13 Individual semi-structured telephone interviews were conducted by an experienced  
14 qualitative researcher (SG) with each physiotherapist (n=9) within two weeks of intervention  
15 delivery completion. A topic guide with specific questions and probes related to fidelity was  
16 developed by the corresponding author (ET) (Supplementary File 3). Interviews were audio-  
17 recorded and transcribed verbatim. Deductive thematic analysis was used to analyse the  
18 interviews as it is a flexible method that works with a range of research questions, including  
19 understanding people's experiences of programmes and health-care interventions.<sup>35</sup>  
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28 Meaningful units of text were highlighted within each interview, then summarised and coded.  
29 Codes dealing with similar issues were grouped across all interviews and refined into themes.  
30 The reliability of themes was established by a second reviewer (AK) who independently  
31 analysed a randomly selected sample of 50% of the transcript extracts using the coding  
32 framework. Percentage agreement was determined between the reviewers' respective coding  
33 of extracts. If agreement was less than 70%, consensus on conflicting decisions was obtained  
34 through discussion.<sup>36</sup>  
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### 41 **Integration**

42 Integration of quantitative and qualitative data occurred at an interpretation level using  
43 triangulation methodology. Specifically, a meta-matrix was created to facilitate comparison  
44 of the findings (Table 5).<sup>37</sup> This involved presenting the quantitative data in a tabular format  
45 alongside summarised qualitative themes, which enabled a transparent approach to  
46 determining convergence, discrepancy or silence across the findings of the data sets.<sup>38</sup>  
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48 Convergence was defined as general agreement between the data sets on the element of  
49 comparison (e.g. overall quantitative fidelity score compared to the majority of  
50 physiotherapist opinions of their fidelity levels), while discrepancy was defined as general  
51 disagreement between the data sets on the element of comparison.<sup>38</sup> Silence was defined as  
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3 where one set of results addressed a theme or example, but the other set of results did not  
4 yield any relevant data.<sup>38</sup>  
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## 9 10 RESULTS

### 11 12 13 Quantitative findings

#### 14 Agreement:

15 Agreement between direct observations and self-report was 74.6%, 75.4% between self-  
16 report and audio-recordings (rater 1) and 86.6% between direct observations and audio-  
17 recordings (rater 1). Inter-rater reliability of audio-recordings (rater 1 vs rater 2) was 81.3%.  
18 Further detail is provided in Supplementary File 4.  
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#### 24 Fidelity of content:

25 Fidelity was found to be high in all assessment methods, with a mean score of 81.7% (range  
26 of 61.1% - 95.8%) for the audio-recordings, 92.7% (85.2% - 96%) for the self-report and  
27 82.7% (72.1% - 100%) for the direct observations. Table 2 details the fidelity results for each  
28 method with scores below 80 (cut-off for 'high' fidelity) shaded. Significant differences  
29 between physiotherapists' individual fidelity scores were found. Fidelity scores were also  
30 found to differ significantly according to the session category (e.g. the category 'Materials'  
31 was delivered with significantly less fidelity than the 'Education' category).  
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<b>Table 2: Fidelity results calculated from % totals</b>			
	<b>Direct Observations (DO)</b>	<b>Self-Report (SR)</b>	<b>Audio 1 (AO)</b>
	<b>% (SD)</b>	<b>% (SD)</b>	<b>% (SD)</b>
<b>Total % mean fidelity score (SD)</b>	82.7% (10)	92.7% (6.4)	81.7% (12)
<b>% mean fidelity score per session (SD)***</b>			
1	88.8% (5.24)	95% (4.5)	91.6% (4.5)
2	82.8% (5.7)	92% (6.9)	86.8% (10.5)
3	85.6% (12.9)	96% (4.2)	81.4% (10.6)
4	83.3% (14.4)	90.9% (8.3)	75% (14)
5	74.1% (11.9)	89.4% (8.1)	78.7% (11)
6	82% (9.6)	92.7% (3.78)	74.9% (12)
<b>% mean fidelity score per site (SD)***</b>			
A (delivered twice, same physiotherapist)	78.7% (7.6)	95% (5.4)	81.3% (11.5)
B (delivered twice, two physiotherapists)	76.7% (5.6)	92.8% (5.3)	71.1% (10)
C (delivered twice, two physiotherapists)	84.8% (11.8)	91.8% (7.7)	84.9% (8.1)
D	87.2% (4)	93.2% (2.9)	87.1% (4.4)
E	83.1% (13)	94.3% (3.8)	88.3% (8.7)

F	72.5%	85.2% (9.6)	72.9% (15)
G	100% (0)	94.7% (4.4)	92.8% (5.4)
<b>% mean fidelity score per category (SD)*</b>			
Materials	72.1% (19.4)	86% (17)	61.1% (29.6)
Introduction and Review	82.6% (16.3)	92.9% (12.8)	76.2% (24.5)
Education	93.3% (8.6)	97.1% (6.6)	95.4% (6.9)
Exercise	80.4% (14)	95.4% (7.1)	82.4% (13)
Review and Planning	77.1% (33)	90.8% (21.6)	69.8% (39.6)
<b>% mean fidelity score per physio (SD)**</b>			
A1	78.8% (7.6)	95.1% (5.4)	81.3% (11.5)
B1	76.1% (7.9)	92.2% (7.2)	72.3% (9.3)
B2	77.5% (0.4)	93.4% (3)	72.6% (12.5)
C1	93.4% (2)	85.2% (4.6)	91% (3.5)
C2	76.2% (11)	98.5% (1.9)	78.8% (6.6)
D1	87.2% (4)	93.2% (2.9)	87.1% (4.4)
E1	83.1% (13)	94.3% (3.8)	88.3% (8.7)
F1	72.5%	85.2% (9.6)	69.8% (14.7)
G1	100% (0)	94.7% (4.4)	95.8% (5.4)
*Significant differences between Categories according to DO (p=0.007), SR (p<0.001) and AO (p<0.001)			
** Significant differences between Physiotherapists according to DO (p=0.019), SR (p=0.004) and AO (p<0.001)			
***Significant differences between Sites (p<0.001) and between Sessions (p=0.007) according to AO, not significantly different			



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according to DO and SR.  
Shaded areas = scores < 80%

For peer review only

### Fidelity of duration:

All methods found a statistically significant difference between the actual duration of the exercise component and its intended duration of 45 minutes (Supplementary File 5). When this was analysed for each individual session for all methods combined, a statistically significant difference ( $p < 0.001$ ) was only found for Session 1 between the actual and intended duration. The difference between the actual and intended duration for all other sessions was not found to be statistically significant ( $p > 0.05$ ).

### Group size – participants in attendance:

The average numbers of participants present for all groups across all sessions was 3, with an SD of 1.3 (Supplementary File 6). Overall, group attendance ranged from one to six participants for any session across both waves. The total number of participants recruited for each group was significantly different between physiotherapists (e.g. seven participants were recruited for the group delivered by physiotherapist F1 compared to only two recruited for the group delivered by D1), as were the numbers of participants present (average group size).

The size of groups did not differ significantly between sessions.

### Factors associated with fidelity:

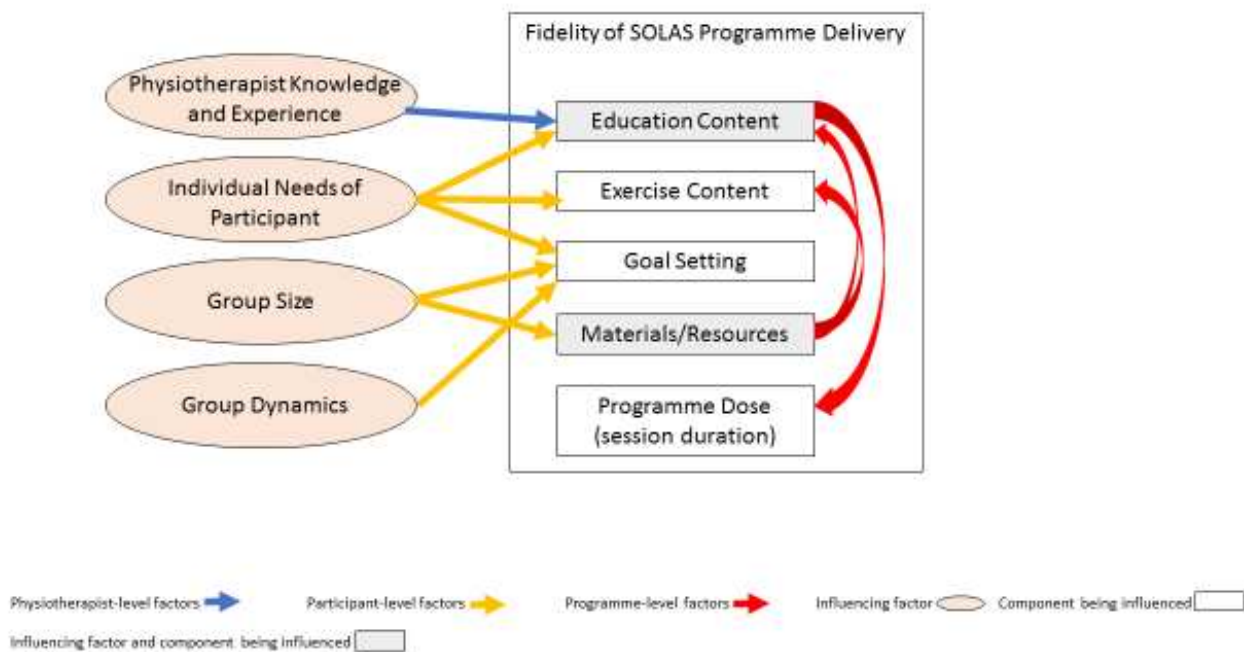
Both direct observation and audio-recorded data showed a significant correlation between fidelity scores and the physiotherapists' post-training evaluation scores. Direct observation data also found a significant negative correlation between group sizes and the fidelity scores. Physiotherapist years qualified and experience of delivering groups were found to have significant, negative correlations with fidelity scores for the audio-recorded and self-report data respectively (Table 3).

Variable	Direct Observations	Self-Report	Audio-Recordings	Statistical Test
Group size (number present)	-0.434 ( $p=0.034$ )*	-0.215 ( $p=0.98$ )	-0.193 ( $p=0.151$ )	Spearman's $r$ ( $p$ -value)
Physiotherapist experience (years qualified)	-0.09 ( $p=0.676$ )	-0.186 ( $p=0.154$ )	-0.346 ( $p=0.008$ )*	

Physiotherapist group experience (years delivering group physiotherapy)	0.171 (p=0.424)	-0.364 (p=0.004)**	0.136 (p=0.312)	
Physiotherapist Post-Training Evaluation Score (%)	0.581 (p=0.003)**	-0.152 (p=0.245)	0.314 (p=0.018)*	
Physiotherapist previous relevant training (yes/no)	$U=33$ (p=0.302)	$U=201$ (p=0.107)	$U = 243$ (p=0.840)	Mann-Whitney U (p-value)
*p is significant at $p<0.05$ , ** $p<0.005$				

### Qualitative findings

Inter-rater reliability of coding achieved 81.6% agreement. Overall, physiotherapists felt that they had delivered the programme with good fidelity. All physiotherapists discussed some deviations from the protocol or adaptations made during delivery, i.e. goal-setting was found to be challenging to complete as intended. Other adaptations either concerned difficulties with use of programme materials (e.g. using the projector) as intended or providing additional information during the education content. Five physiotherapists also discussed deviation from protocol in relation to duration, mostly during the first session, with one stating that her *'time management around the education wasn't always exactly what it should have been'* (B1, transcript line 278-286). In terms of factors that influenced fidelity (i.e. reasons discussed for the aforementioned adaptations and deviations), six themes were found that were structured into three levels of factors – physiotherapist, participant and programme-level (Figure 2).



**Figure 2:** Visual representation of themes of qualitative interviews – factors influencing fidelity of SOLAS delivery

At the physiotherapist level, eight of the nine physiotherapists felt that knowledge of the content of the SOLAS programme facilitated their delivery of the education session and made it easier. Conversely, deviations from protocol within the education content discussed by six physiotherapists were due to the provision of additional information which was influenced by their previous experiences of delivering similar groups (e.g. talking more about pain pathophysiology because of previous classes delivered on this topic). This formed the theme '*Physiotherapist knowledge and experience influenced delivery of SOLAS - education content*'.

At the participant level, five physiotherapists felt that participants' individual needs such as their understanding of content or language literacy levels influenced the delivery of education and exercise components and that adaptation sometimes occurred in response to these needs, creating the theme of '*Individual needs influenced delivery of SOLAS - education, exercise, goal-setting*'. The number of participants present was discussed by seven physiotherapists as another participant-level factor that influenced fidelity of delivery and formed the participant-

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3 level theme of '*Group size influenced delivery of SOLAS - goal-setting, use of materials*'. A  
4 further participant-level theme was '*Group dynamics influenced delivery of SOLAS - goal-*  
5 *setting*' as four physiotherapists felt that groups with good dynamics and interaction between  
6 participants led to better group discussions and better facilitation of goal setting.  
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11 The '*Amount of education content influenced delivery of SOLAS – duration* was a  
12 programme-level factor discussed by six physiotherapists, who felt that the amount of  
13 education content that was involved in the first session led to more time spent on the  
14 education aspect than intended as per protocol. Finally, all nine physiotherapists believed that  
15 the good resources (e.g. booklets and handouts, venue space) enhanced and facilitated the  
16 delivery of the programme as intended and that occasionally poor or problematic resources  
17 (e.g. lack of venue security) negatively influenced the delivery of the programme as intended.  
18 This created the theme '*Resources/materials influenced delivery of SOLAS – education and*  
19 *exercise content*'. Exemplary quotes are provided in Table 4.  
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<b>Factor level</b>	<b>Theme</b>	<b>Exemplary quote (Physiotherapist code, transcript line)</b>
<b>Physiotherapist</b>	Physiotherapist knowledge and experience influenced delivery of SOLAS - education content	<i>'In my previous experience I would have done a lot more actually on the pain side of things...so in my previous class I would have had, you know, maybe one full class on maybe pain perception and, kind of, the influence of emotion and feelings...so I think I would have probably maybe talked a lot more around that pain section than maybe somebody else would have'. (C1, 75-99)</i>
<b>Participant</b>	Individual needs influenced delivery of SOLAS - education, exercise, goal-setting	<i>'People don't like writing them [action plans] there and then you know with pencils given and whatever - yes it's very hard to get people to write down things like that....Where I work there is a lot of people health literacy is very low...so therefore that's a challenge for them...so I tend to be very careful about pushing it out really' (F1, 141-187)</i>
<b>Participant</b>	Group size influenced delivery of SOLAS – goal-setting, use of materials	<i>'The only thing I might find a little bit hard would be the goal setting. I suppose you'd - that would be a bit more challenging because you'd have more numbers in the group' (G1, 118-132)</i>
<b>Participant</b>	Group dynamics influenced delivery of SOLAS - goal-setting	<i>'People were willing to engage you know as a group, in their goals.....so that made it very easy that we didn't actually have any clients that weren't willing to talk in the group, so it was very much an interactive group' (E1, 225-231)</i>
<b>Programme</b>	Amount of education content influenced delivery of SOLAS – duration	<i>'I found the content in week one was nearly too much... by the time I finished talking and ran through the exercises, the hour and a half was finished. And so nobody actually practiced any of the exercises on the first day' (B2, 96-106)</i>
<b>Programme</b>	Resources/materials	<i>'The slides didn't work for me this time....You can't lock that room.... once or twice I didn't</i>

	influenced delivery of SOLAS – education and exercise content	<p><i>bring the laptop at all and I just had to print it out, all of the slides on A4 laminate and so we talked all the slides....</i> ' (F1, 207-240)</p> <p><i>'I think I only left out maybe three [exercise] stations, something like that. Because we didn't have a bouncer and...we didn't have a bed'</i> (C1, 113-121)</p> <p><i>'Nothing but positive feedback for all the content and the-the resources...I just think they complimented the - the education fantastically, I just thought they added much more to the programme than not having these resources.'</i> (E1, 414-415)</p>
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### **Integrating qualitative and quantitative findings**

Each theme was further analysed according to the quantitative data comparing physiotherapists who scored 'high' (i.e.  $\geq 80\%$ ; physiotherapists D1, C1, E1 and G1) to those who scored 'moderate' (i.e.  $\geq 50-79\%$ ; B1, B2, C2 and F1). Physiotherapist A1 was not included in this analysis as her score was categorised as 'moderate' by direct observations and 'high' by audio-recorded data at 78.7% and 81.3% respectively. A difference between these physiotherapist groups was found in only one theme, '*Group size influenced delivery of SOLAS*'. Physiotherapists who scored higher on the fidelity assessments (average group size of 2.5 participants), believed it was easier to deliver goal-setting as intended with smaller groups. Conversely, physiotherapists with moderate fidelity scores (average group size of 3.7 participants) felt it was harder to facilitate goal-setting as intended with less numbers and believed it would be easier with bigger groups due to better engagement and group discussion. Further details of the triangulation are provided in Table 5 where a meta-matrix was used to compare between findings from both datasets. For the most part, convergence was found between the qualitative and quantitative data, though four qualitative themes relating to influencing factors had no corresponding quantitative data (silence). No areas of discrepancy were found.



<b>Table 5: Triangulation of quantitative and qualitative results – convergence and discrepancy of findings</b>				
<b>Outcome of interest</b>	<b>Quantitative fidelity findings</b>		<b>Qualitative interview findings</b>	<b>Convergence/ Discrepancy/ Silence</b>
Fidelity findings:	<b>Overall fidelity of content scores</b>	High fidelity (>80%) <ul style="list-style-type: none"> <li>• Direct Observations: 82.7%</li> <li>• Self-Report: 92.7%</li> <li>• Audio-Recordings: 81.7%</li> </ul>	Overall physiotherapists felt that their fidelity was good. Some adaptations and deviations were discussed as occurring in the delivery of the following aspects of the programme: <ul style="list-style-type: none"> <li>• Goal-setting (Introduction and Review, Review and Planning categories)</li> <li>• Education content</li> <li>• Exercise content</li> <li>• Use of programme materials</li> <li>• Duration of session 1</li> </ul>	Convergence
	<b>SOLAS categories scoring below 80% fidelity</b>			
	<i>Materials</i>	Moderate fidelity (50-79%) <ul style="list-style-type: none"> <li>• Direct Observations: 72.1%</li> <li>• Audio-Recordings: 61.1%</li> </ul>		
	<i>Introduction and Review</i>	<ul style="list-style-type: none"> <li>• Audio-recordings: 76.2%</li> </ul>		
	<i>Review and Planning</i>	<ul style="list-style-type: none"> <li>• Direct Observations: 77.1%</li> <li>• Audio-Recordings: 69.8%</li> </ul>		
	<b>Fidelity of duration – sessions significantly different to intended duration</b>			
<i>Session 1</i>	<ul style="list-style-type: none"> <li>• Education duration: 58.9’*</li> <li>• Exercise duration: 31.4’*</li> </ul>			
Factors influencing	<b>Correlation between quantitative variables and fidelity scores</b>		<i>Theme 1: Physiotherapist knowledge and experience influenced delivery of SOLAS - education content</i>	Convergence

fidelity findings:	Physiotherapist Experience (years qualified)	<ul style="list-style-type: none"> <li>• Audio-recordings: -0.333 (p=0.011)***</li> </ul>		
	Physiotherapist Group Experience (years delivering group physiotherapy)	<ul style="list-style-type: none"> <li>• Self-report: -0.430 (p=0.018)***</li> </ul>		
	Physiotherapist Post-Training Evaluation Score (%)	<ul style="list-style-type: none"> <li>• Direct observations: 0.581 (p=0.003)**</li> <li>• Audio-recordings: 0.314 (p=0.018)***</li> </ul>	<i>Theme 1: Physiotherapist knowledge and experience influenced delivery of SOLAS - education content</i>	Convergence
	Group size (average numbers of participants present)	<ul style="list-style-type: none"> <li>• Direct observations: -0.434 (p=0.034)***</li> </ul>	<i>Theme 3: Group size influenced delivery of SOLAS – goal-setting, use of materials</i>	Convergence
	No corresponding quantitative data			<i>Theme 2: Individual needs influenced delivery of SOLAS - education, exercise, goal-setting</i> <i>Theme 4: Group dynamics influenced delivery of SOLAS - goal-setting</i> <i>Theme 5: Amount of education content influenced delivery of SOLAS – duration</i> <i>Theme 6: Resources/materials influenced delivery of</i>

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		<i>SOLAS – education and exercise content</i>	
*p<0.001, **p<0.005, ***p<0.05			

For peer review only

## DISCUSSION

The aim of this mixed methods study was to explore and evaluate fidelity of delivery within a feasibility trial of a complex behaviour change intervention using multiple assessment methods. The study found good agreement between researcher-delivered direct observation and audio-recorded fidelity assessment methods, with lower agreement found between provider self-report and researcher-delivered methods. The intervention content was delivered overall with high fidelity, with some variation between physiotherapists and between certain intervention categories. The intervention duration was found to have deviated significantly from intended during the first session only. Subsequently, qualitative interviews with physiotherapists confirmed these fidelity findings. Finally, both qualitative and quantitative data showed that physiotherapists' knowledge and previous experience, as well as the group size, were factors that influenced their fidelity of intervention delivery. The qualitative data contributed further, and postulated additional participant and programme-level factors as aspects that also influenced the overall fidelity results.

Agreement between direct observations and audio-recordings for assessing the fidelity of delivery was found to be excellent.<sup>39</sup> Agreement between both of these methods and provider self-report assessment was lower, as providers consistently rated themselves higher than the independent raters. These findings are perhaps unsurprising, as both direct observations and audio-recordings were rated by the same researcher, and numerous previous studies have shown that providers' subjective assessments of fidelity are often rated higher than independent assessments.<sup>31,32,40</sup> Taking direct observations as the commonly-cited 'gold standard',<sup>11,18,20</sup> these findings reinforce that self-report methods may not be the most accurate method for assessing fidelity in a complex behaviour change study. However, they may still have their place for recording data and also for enhancing fidelity to the protocol by serving as an aide memoire for providers.<sup>41</sup> Although direct observations and audio-recordings have their own limitations<sup>24,42</sup>, previous piloting of these assessment methods found that they were feasible and acceptable to physiotherapists.<sup>27</sup> Additionally, the good agreement between audio-recordings and direct observations found in this study suggests that audio-recordings may be a viable alternative with limited resources, as has been done in similar interventions.<sup>43</sup> However, where resources allow, a combination of multiple quantitative methods may provide the most in-depth assessment of fidelity.

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3 One of the key study findings of this study was reinforcing the value of using mixed methods  
4 research for the assessment of fidelity. This approach was emphasised in the recent MRC  
5 guidelines for conducting process evaluations of complex interventions<sup>6</sup>, and is becoming  
6 increasingly used in the widespread implementation of evidence-based interventions<sup>44</sup> but  
7 does not yet appear to be common practice within fidelity assessments of behaviour change  
8 interventions.<sup>10,21</sup> The integration of quantitative and qualitative results enabled the  
9 triangulation of findings to provide a better overall picture of the fidelity of the SOLAS  
10 intervention and its influencing factors. The importance of the qualitative contribution to  
11 answering the ‘why’ question is evident in the fact that the physiotherapist interviews  
12 unearthed strong participant and programme-level factors associated with fidelity results that  
13 were not apparent from the quantitative data alone. Whilst this may be predominantly due to  
14 the focus of the quantitative analysis on physiotherapist-level variables which were chosen  
15 based on existing literature, the participant and programme-level factors identified by this  
16 analysis such as group dynamics or amount of programme content may have been difficult to  
17 quantitatively analyse to demonstrate association with fidelity results.  
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30 This study found that the factors that may influence the fidelity of an interventions’ delivery  
31 can occur on three levels – provider, participant and programme. Where previous studies  
32 have explored factors that have influenced fidelity of intervention delivery, many have  
33 focused solely on provider-level factors, demonstrating associations between fidelity and  
34 factors such as provider training or skills.<sup>13,19,21,45</sup> The findings of this study have valuable  
35 implications for future studies that aim to assess and enhance fidelity of similar interventions  
36 as they indicate that planning for fidelity should include considering potential influencing  
37 factors at each of these three levels. These results are consistent with recent conclusions by  
38 Masterson-Algar et al. in a stroke rehabilitation setting<sup>14</sup> who found that investigating  
39 fidelity within clinical trials should also take the individual needs of patients into account,  
40 and also concur with the findings of an education-based intervention that found the most  
41 common reason for adaptation within intervention delivery was insufficient time.<sup>46</sup>  
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51 On the physiotherapist-level, better knowledge of the intervention content and structure was  
52 found to positively correlate with quantitative fidelity scores, with a causative link  
53 established via the qualitative investigation. This echoes previous findings by Huijg et al.  
54 who showed that physiotherapist skill level was one of the most important predictors of  
55 fidelity.<sup>21</sup> A more targeted approach to enhancing fidelity in future interventions may  
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3 therefore be warranted, such as identifying physiotherapists at higher risk of lower fidelity  
4 using post-training evaluation scores and employing more focused fidelity assessment of  
5 delivery or further training for these providers,<sup>13</sup> as has been previously employed in similar  
6 interventions.<sup>10,43</sup> The results of the study also showed that physiotherapists with more  
7 experience of certain aspects tended to emphasise these at the expense of delivering other  
8 components as comprehensively as intended in the protocol. These experience-based  
9 adaptations invoke the well-established issue of adaptation versus fidelity. For years, research  
10 has debated the concept of fidelity versus adaptation, with the case made for both strict  
11 fidelity and for modifying interventions.<sup>47</sup> A third view is that both fidelity and adaptation  
12 are essential, and achieving an appropriate balance between both can allow an intervention to  
13 maximise its effectiveness, while being generalizable and flexible enough to be  
14 implementable.<sup>48,49</sup> To achieve this, our fidelity checklists included components that  
15 encouraged elements of treatment individualisation (e.g. individualised feedback regarding  
16 exercises). However, it may be that these checklists still did not allow for enough  
17 individualisation within delivery, an aspect that should be considered by other researchers  
18 seeking to conduct similar fidelity assessments.  
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31 A limitation of this study was the timing of the interviews, which did not allow a 'pure'  
32 convergent/triangulation design. Typically, the qualitative and quantitative methods occur  
33 concurrently in this design,<sup>28</sup> however, they were scheduled to take place after  
34 physiotherapists had experienced delivery of an entire six-week SOLAS intervention.  
35 Although a sequential explanatory design<sup>30</sup> where quantitative results were analysed prior to  
36 completing the interviews might have enabled further probing of the factors influencing  
37 fidelity, interviews were conducted within two weeks of the intervention completion to  
38 minimise recall bias. Due to time constraints it was not possible to have the quantitative data  
39 collected and analysed beforehand. Finally, this study mostly focuses on the adherence of  
40 delivery (e.g. intervention content and duration) and does not address the *quality* or  
41 competence of delivery of SOLAS (e.g. interpersonal or communication style of the  
42 physiotherapist), or use of specific BCTs, which is being addressed in a separate publication.  
43 This study also does not examine the broader aspects of fidelity such as provider training or  
44 participant receipt, as these were beyond the scope of this publication and will be addressed  
45 in a future paper.  
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## 58 CONCLUSIONS

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3 In process evaluations and fidelity assessments of large scale complex interventions it is often  
4 recommended to complete and report the results of the fidelity assessment before the trial  
5 outcomes so as not to bias reporting.<sup>50</sup> Future work will investigate the relationship between  
6 this evaluation of fidelity of delivery, the SOLAS feasibility trial outcomes (analysis  
7 currently underway) and the evaluation of fidelity of BCT delivery, enabling a potentially  
8 more insightful and accurate interpretation of findings. This study also has valuable  
9 implications for further research and the overall science of fidelity as it contributes much-  
10 needed information to the limited current evidence for the application of fidelity assessment  
11 methods within the area of complex behaviour change. The findings have demonstrated how  
12 multiple quantitative methods can be used to assess the fidelity of delivery of a complex  
13 behaviour change intervention, and that a combination of methods may be most suitable,  
14 depending on their acceptability and available resources. We have also shown how the use of  
15 a mixed methods approach, integrating both quantitative and qualitative data, provides a more  
16 insightful understanding of the factors influencing fidelity.  
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## **AUTHORS' CONTRIBUTION**

ET conceptualized and designed the study and conducted the data collection and analysis. JM and DAH provided guidance on the design. DAH is the principal investigator of the SOLAS trial and obtained funding for this study within the trial. All authors provided methodological consultation and were involved in substantial contributions to reviewing of the drafts. All authors approved the final version of the manuscript.

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## **CONFLICTS OF INTEREST**

None



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## Supplementary Files

### Supplementary File 1: Quantitative fidelity checklists used

#### INTERVENTION SESSION CHECKLIST (OBSERVATION/AUDIO-RECORDING):

##### Cover sheet (completed for each session)

<b>Date:</b>	
<b>Venue:</b>	
<b>Physiotherapist Name:</b>	
<b>Other staff involved:</b>	Name(s): Role: (e.g. set-up/delivery/support)
<b>Session number (tick):</b>	1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/>
<b>Start time (class):</b>	
<b>Finish time (class):</b>	
<b>Time spent on education (mins):</b>	
<b>Time spent on exercise (mins):</b>	
<b>Method of Observation:</b>	In-vivo/Audio-recording
<b>Adverse event(s)/issue(s) (circle):</b>	If yes give brief details:
Y/N	

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<b>Deviations from protocol/proscribed components delivered?</b>	Yes/No Details:						
<b>General notes on fidelity of session:</b>							
<b>INTERVENTION COMPONENT CHECKLIST:</b>				<b>YES (2)</b>	<b>NO (0)</b>	<b>ATTEMPTED (1)</b>	<b>N/A</b>
<b>Session 1:</b>							
<b>Materials</b>							
Intervention folder given to participants				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Use of participant intervention folder actively facilitated throughout session				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Name stickers/badges given to participants				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Pens offered/provided				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Powerpoint slides used				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Introduction</b>							
Introductions/welcome made				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Set clear expectations - aims, content and structure of programme addressed				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Rationale for weekly attendance provided				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Education</b>							

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4	<b>Rationale for self-management provided</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
5	<b>Posture addressed</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
6	<b>Cycle of change addressed</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
7	<b>Disease characteristics, prevalence and causes of OA/CLBP addressed</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
8	<b>Recommended activity levels/benefits of exercise addressed</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
9	<b>Individual reflection on activity/recommendations facilitated</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
10					
11	<b>Goal setting introduced</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
12	<b>Action planning introduced</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
13	Attention drawn to <b>Action Plan sheets</b> within intervention folder, <b>encouraged use</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
14					
15	Attention drawn to <b>Activity Diaries</b> within intervention folder, <b>encouraged use</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
16					
17	Participants given a chance/encouraged to <b>contribute to discussion</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
18					
19	<b>Exercise</b>				
20	<b>Room set up</b> for exercise (equipment, sheets)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
21	<b>Protocol exercises demonstrated</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
22	Attention drawn to <b>Exercise Programme Diary</b> within intervention folder, <b>encouraged use</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
23					
24	<b>Rationale for exercises provided</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
25					
26	Participants given a chance to <b>attempt and practice protocol</b> exercises	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
27	<b>Individual feedback provided</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
28					
29	<b>Review and Planning</b>				
30	Session review - <b>activity levels and goal setting recap</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
31	<b>Proscribed components delivered?</b>	<input type="checkbox"/> (-2)	<input type="checkbox"/>		
32	Total score (Yes = 2, Attempted = 1, No =0)				
33	Overall Adherence score				
34					
35					
36	<b>Session 2:</b>				
37					
38					
39	<b>INTERVENTION COMPONENT CHECKLIST:</b>	<b>YES (2)</b>	<b>NO (0)</b>	<b>ATTEMPTED (1)</b>	<b>N/A</b>
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<b>Materials</b>				
Use of <b>participant intervention folder</b> actively facilitated throughout session	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Name stickers/badges</b> given to participants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Pens offered/provided</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Pedometers</b> offered	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Powerpoint slides</b> used	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Recap and Review</b>				
<b>Welcome back</b> made	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Review</b> of previous week <b>activities/action plans</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Education</b>				
<b>Set clear expectations – content of session</b> outlined	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Activity-rest cycle</b> and <b>pacing</b> explained	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Individual reflection</b> on <b>current pacing/activity-rest</b> facilitated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Factors influencing pain</b> addressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Goal setting</b> facilitated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Action planning</b> facilitated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Action Plan sheets</b> use encouraged/facilitated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Attention drawn to <b>Walking/Activity Diary</b> within intervention folder, <b>encouraged use</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Participants given a chance/encouraged to <b>contribute to discussion</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Exercise</b>				
<b>Room set up</b> for exercise (equipment, sheets)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Protocol exercises demonstrated</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Exercise Programme Diary</b> use encouraged	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Rationale</b> for <b>exercises</b> provided	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Participants given a chance to <b>attempt and practice protocol</b> exercises	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Individual feedback</b> provided	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Session Planning and Review</b>				
Session review - <b>goal setting and action planning recap</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Proscribed components delivered?</b>	<input type="checkbox"/> (-2)	<input type="checkbox"/>		
Total score (Yes = 2, Attempted = 1, No =0)				

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Overall Adherence score				
<b>Session 3:</b>				
<b>INTERVENTION COMPONENT CHECKLIST:</b>	<b>YES (2)</b>	<b>NO (0)</b>	<b>ATTEMPTED (1)</b>	<b>N/A</b>
<b>Materials</b>				
Use of <b>participant intervention folder</b> actively facilitated <b>throughout</b> session	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Tape measures</b> offered	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Pens offered/provided</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Powerpoint slides</b> used	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Recap and Review</b>				
Previous week <b>Activity Action Plan</b> reviewed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Problem-solving</b> of previous week <b>Activity Action Plan</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Action Plan sheets</b> use encouraged/facilitated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Education</b>				
<b>Set clear expectations – content of session</b> outlined	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Obesity and effect on pain</b> addressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Balance between weight/activity</b> addressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Individual reflection</b> on <b>weight/activity</b> balance facilitated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Skills for maintaining healthy weight</b> addressed (e.g. waist measurement, food diary)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Attention drawn to <b>Healthy Eating Booklet</b> within intervention folder, <b>encouraged use</b>				
Attention drawn to <b>Walking/ Activity Diary</b> within intervention folder, <b>encouraged use</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Attention drawn to <b>Food &amp; Exercise Diary</b> within intervention folder, <b>encouraged use</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Participants given a chance/encouraged to <b>contribute to discussion</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Exercise</b>				
<b>Room set up</b> for exercise (equipment, sheets)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Protocol exercises demonstrated</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



Exercise Programme Diary use encouraged	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Rationale for exercises provided	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Participants given a chance to attempt and practice protocol exercises	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Individual feedback provided	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Session Planning and Review</b>				
Session review - goal setting and action planning recap integrating food and exercise diary	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Proscribed components delivered?	<input type="checkbox"/> (-2)	<input type="checkbox"/>		
Total score (Yes = 2, Attempted = 1, No =0)				
Overall Adherence score				
<b>Session 4:</b>				
<b>INTERVENTION COMPONENT CHECKLIST:</b>				
	<b>YES (2)</b>	<b>NO (0)</b>	<b>ATTEMPTED (1)</b>	<b>N/A</b>
<b>Materials</b>				
Use of participant intervention folder actively facilitated throughout session	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Pens offered/provided	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Powerpoint slides used	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Midway Recap and Review</b>				
Previous week Activity Action Plan reviewed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Problem-solving of previous week Activity Action Plan	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Action Plan sheets use encouraged/facilitated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Walking/ Activity Diary use encouraged	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Education</b>				
Set clear expectations – content of session outlined	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Rationale for using pain relief given (e.g. pain pathway explained)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Methods of pain relief addressed (e.g. medication, heat/ice, TENS/acupuncture)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Individual reflection on use of pain relief facilitated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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Participants given a chance/encouraged to <b>contribute to discussion</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Exercise</b>				
<b>Room set up</b> for exercise (equipment, sheets)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Protocol exercises demonstrated</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Exercise Programme Diary</b> use encouraged	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Rationale for exercises</b> provided	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Participants given a chance to <b>attempt and practice protocol</b> exercises	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Individual feedback</b> provided	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Session Planning and Review</b>				
Session review - <b>goal setting and action planning</b> recap	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Proscribed components delivered?</b>	<input type="checkbox"/> (-2)	<input type="checkbox"/>		
Total score (Yes = 2, Attempted = 1, No =0)				
Overall Adherence score				
<b>Session 5:</b>				
<b>INTERVENTION COMPONENT CHECKLIST:</b>	<b>YES (2)</b>	<b>NO (0)</b>	<b>ATTEMPTED (1)</b>	<b>N/A</b>
<b>Materials</b>				
Use of <b>participant intervention folder</b> actively facilitated <b>throughout</b> session	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Pens offered/provided</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Relaxation CD</b> offered	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Powerpoint slides</b> used	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Recap and Review</b>				
Previous week <b>Activity Action Plan</b> reviewed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Problem-solving</b> of previous week <b>Activity Action Plan</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Action Plan sheets</b> use encouraged/facilitated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Walking/ Activity Diary</b> use encouraged	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Education</b>				
<b>Set clear expectations – content of session</b> outlined	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Recognising and managing flare-ups addressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Individual reflection about flare-ups facilitated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Effect of mood on pain addressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Participants given a chance/encouraged to contribute to discussion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Exercise</b>				
Room set up for exercise (equipment, sheets)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Protocol exercises demonstrated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Exercise Programme Diary use encouraged	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Rationale for exercises provided	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Participants given a chance to attempt and practice protocol exercises	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Individual feedback provided	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Relaxation Session</b>				
Relaxation techniques explained and practiced	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Session Planning and Review</b>				
Session review - goal setting and action planning recap with integration of relaxation techniques	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Proscribed components delivered?	<input type="checkbox"/> (-2)	<input type="checkbox"/>		
Total score (Yes = 2, Attempted = 1, No =0)				
Overall Adherence score				
<b>Session 6:</b>				
<b>INTERVENTION COMPONENT CHECKLIST:</b>				
	<b>YES (2)</b>	<b>NO (0)</b>	<b>ATTEMPTED (1)</b>	<b>N/A</b>
<b>Materials</b>				
Use of participant intervention folder actively facilitated throughout session	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Pens offered/provided	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Handouts on local resources and supports provided	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Powerpoint slides used	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Recap and Review</b>				
Previous week Activity Action Plan reviewed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Problem-solving of previous week Activity Action Plan	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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<b>Action Plan sheets</b> use encouraged/facilitated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Walking/ Activity Diary</b> use encouraged	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Education</b>				
<b>Set clear expectations – content of session</b> outlined	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Core skills of programme</b> reviewed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Aims of long-term self-management</b> addressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Local resources and supports</b> discussed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Participants given a chance/encouraged to <b>contribute to discussion</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Exercise</b>				
<b>Room set up</b> for exercise (equipment, sheets)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Protocol exercises demonstrated</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Exercise Programme Diary</b> use encouraged	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Rationale for exercises</b> provided	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Participants given a chance to <b>attempt and practice protocol</b> exercises	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Individual feedback</b> provided	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Session Planning and Review</b>				
Session review – <b>long term goal setting and action planning</b> recap	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Activity diaries <b>use recorded</b> (if willing)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Proscribed components delivered?</b>	<input type="checkbox"/> (-2)	<input type="checkbox"/>		
Total score (Yes = 2, Attempted = 1, No =0)				
Overall Adherence score				

**Yes** = Fully addressed by the Physiotherapist – could not do more

**Attempted** = Reasonable attempt made to address this – could do more

**No** = No attempt made to address this

**INTERVENTION SESSION CHECKLIST (SELF-REPORT)**

Self-report checklists covered similar components to observation and audio as provided above - different cover sheet (completed for each session) provided below

<b>PCCC Site:</b>	<b>Date:</b>	<b>Class: circle</b> 1 2 3 4 5 6	<b>Physiotherapist Name:</b>
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**PERSONNEL**

<b>Other staff involved in setting up class:</b>	Yes <input type="checkbox"/> No <input type="checkbox"/>	<b>Names/Staff Grade:</b>
<b>Other staff involved in providing class:</b>	Yes <input type="checkbox"/> No <input type="checkbox"/>	<b>Names/Staff Grade:</b>

**ATTENDANCE**

	<b>Present</b>	<b>Absent</b>
<b>Number of Clients:</b>		
<b>Names of non-attenders:</b>	<b>Reasons for non-attendance [if known]</b>	
1.		
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**CLASS PREPARATION**

<b>Time to review materials [mins]:</b>	<b>Time to set up class [mins]:</b>	<b>Time to take down class [mins]:</b>
<b>Start Time:</b>	<b>End Time:</b>	<b>Comments:</b>

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**CLASS DELIVERY**

	<b>Education</b>	<b>Exercise</b>
<b>Time to deliver [mins]:</b>		
<b>Comments:</b>		
<b>Deviations from protocol: Content/time</b>	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>If 'yes' give details and reason[s]</b>		

**TREATMENT-RELATED EVENT – any unforeseen event/issue should be reported to Deirdre Hurley**

<b>During class:</b> Yes <input type="checkbox"/> No <input type="checkbox"/>	<b>After class:</b> Yes <input type="checkbox"/> No <input type="checkbox"/>	<b>Reported to Deirdre:</b> Yes <input type="checkbox"/> No <input type="checkbox"/>
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When patient is discharged please give this completed form to UCD Research Physiotherapist or scan and email to [physiostudy@ucd.ie](mailto:physiostudy@ucd.ie)

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Supplementary File 2: Physiotherapist baseline characteristics										
	Wave 1				Wave 2					
Physiotherapy Site	A	B	C	D	A	B	C	E	F	G
Physiotherapist	A1	B1	C1	D1	A1	B2	C2	E1	F1	G1
Gender	F	F	F	M	F	F	F	F	F	F
Experience (years qualified)	5	25	8	12	5	25	10	6	19	11
Group experience (years delivering group physiotherapy)	1	3	8	2	1	10	3	1	15	7
Post-training evaluation score (%)	74%	81.5%	90.5%	83.4%	74%	88.5%	81.8%	88.2%	78.1%	94.4%
Previous training in similar interventions (Y/N)	N	Y	Y	Y	N	Y	Y	Y	Y	Y
F= female, M=male, Y=yes, N=no										

## Supplementary File 3: Physiotherapist interviews topic guide

### SOLAS Programme Semi-Structured Interviews with Physiotherapists

#### Interview Schedule

**Ice-breaker** – describe your experience in running group-based programmes for these or other populations before this study. How many weeks of the SOLAS programme did you deliver?

#### Therapist Views on Experience of Delivering the Programme

- What are your overall impressions of the programme having delivered it for first/second time?
  - Content overall and week by week –education and exercise components – time for each- managing group dynamics – mixed ability/diagnosis and ages of clients
- What aspects did you find easy/challenging to deliver?  
[content/communication/behaviour change/goal setting/action planning – these were emphasised in training]
- Views on feasibility of class size of up to 8 clients with one physiotherapist to deliver?  
[none delivered a class of this size – their views on running small numbers v the target of 8]
- How well do you feel you delivered the programme as intended from the training received?
  - Following the slide content/script – was it difficult/did you want to edit - which parts?
  - Content/needs supportive delivery style/ behaviour change techniques
  - Views on giving advice/setting goals with patients and following through and being needs supportive (using SDT) e.g. using non-controlling language, enabling patient input and choice; providing positive and personalised feedback to patients?
  - Difficult/constrained by research?
- For the aspects not delivered as planned from training give reasons –
  - prompt on potential barriers to delivery [the availability of resources (e.g. staffing, suitable venue, administrative staff, time constraints); appropriate patient selection and screening, patient uptake and engagement with programme and the potential need to individualise treatment within group]
- How much additional work did delivering the programme and participating in this study place upon you? [Specify – preparation time – reading the manual and supplementary materials, setting up the venue, time to deliver – on top of other work, completion of treatment record forms after each class, completion of post training questionnaires]?
  - Is this acceptable? What modifications would you suggest for future waves?
- What are your impressions of the resources provided to you to support delivery of the programme? [Training Manual /Intervention Manual/Intervention Slides/SOLAS poster]
  - How much have you used them? What was useful/not useful in terms of helping you deliver the programme as intended?
  - Views on continuing to use powerpoint versus flip chart or handouts only?
  - Suggestions for modifications for future waves
- What are your impressions of the venue in terms of its suitability for delivering the programme? [Prompt – accessibility, space, equipment for delivering education and exercise component number of stations, sound quality to allow communication to the



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3 group/individuals during exercises  
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6 **Views on sustainability of the Programme**

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- 8 • What is your opinion of the feasibility of delivering the programme in the future within the study/within normal practice?
  - 9 • Would you deliver the programme outside the study?
  - 10 • How would you deliver it? What materials would you use? What would you leave out? Who would you deliver it to?
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14 **Views on Research Elements of the Programme**

- 15
- 16 • Views on research elements of the programme [pre and post training questionnaires, direct observation during classes, audio recordings, treatment record forms]
    - 17 ○ Intrusiveness/time/feasibility Any suggestions for modifications for future waves
  - 18 • Views on level and modes of communication with the research team throughout the study from training to completion of this wave
    - 19 ○ Suggestions for modifications for future waves
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peer review only

<b>Supplementary File 4: Agreement between assessment methods</b>				
	Direct Observation v Self-Report (n=24)	Direct Observation v Audio- Recordings (n=24)	Audio-Recordings v Self-Report (n=60)	Audio-Recordings Rater 1 v Rater 2 (Inter-rater reliability) (n=12)
<b>Overall agreement</b>	74.6%	86.6%	75.4%	84.6%
<b>% Agreement per category:</b>				
<b>Materials</b>	74.5%	82.67%	70.1%	84.6%
<b>Introduction and Review</b>	65.3%	86.5%	57%	81.6%
<b>Education</b>	84.6%	90.3%	87.3%	76.7%
<b>Exercise</b>	70.8%	86%	78%	83.3%
<b>Review and Planning</b>	50%	76.2%	46%	100%