# Feasibility cluster randomised controlled trial evaluating a theory-driven group-based complex intervention versus usual physiotherapy to support self-management of osteoarthritis and low back pain (SOLAS)

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# Abstract

Background The Self-management of Osteoarthritis (OA) and Low back pain (LBP) through Activity and Skills (SOLAS) theory-driven group-based complex intervention was developed primarily for the evaluation of its acceptability to patients and physiotherapists and the feasibility of trial procedures, to inform the potential for a definitive trial. Methods This assessor-blinded multicentre two-arm parallel cluster randomised controlled feasibility trial compared the SOLAS intervention to usual individual physiotherapy (UP; pragmatic control group). Patients with OA of the hip, knee, lumbar spine and/or chronic LBP were recruited in primary care physiotherapy clinics (i.e. clusters) in Dublin, Ireland between September 2014 and November 2015. The primary feasibility objectives were evaluated using quantitative methods and individual telephone interviews with purposive samples of participants and physiotherapists. A range of secondary outcomes were collected at baseline, 6 weeks (behaviour change only), 2 months and 6 months to explore the preliminary effects of the intervention. Analysis was by intention-to-treat according to participants' cluster allocation and involved descriptive analysis of the quantitative data and inductive thematic analysis of the qualitative interviews. A linear mixed model was used to contrast change over time in participant secondary outcomes between treatment arms, while adjusting for study waves and clusters. Results 14 clusters were recruited (7 per trial arm), each cluster participated in two waves of recruitment, with the average cluster size below the target of six participants (Intervention: mean (SD) =4.92 (1.31), range 2-7; UP: mean (SD) =5.08 (2.43), range 1-9). 120 participants (83.3% of n=144 expected) were recruited (Intervention n=59; UP n=61), with follow up data obtained from 80.8% (n=97) at 6 weeks, 84.2% (n=101) at 2 months and 71.7% (n=86) at 6 months. Most participants received treatment as allocated (Intervention n=49; UP n=54). The qualitative interviews (12 participants; 10 PTs) found the Intervention and trial procedures acceptable and appropriate, with minimal feasible adaptations required. Linear mixed methods showed improvements in most secondary outcomes at 2 and 6 months with small between group effects. Conclusions While the SOLAS intervention and trial procedures were acceptable to participants and PTs, the recruitment of enough participants is the biggest obstacle to a definitive trial. Trial Registration: ISRCTN Registry, ISRCTN49875385, Registered 26 March 2014. https://doi.org/10.1186/ISRCTN49875385


# Introduction

The successful implementation of a standardised, evidence-based group programme to support self-management (SM) for people with chronic musculoskeletal pain is a priority for primary care physiotherapy (PT) in Ireland [1]. While international clinical guidelines endorse self-management, exercise and physical activity for osteoarthritis (OA) and low back pain (LBP) [2–6], the evidence for the effectiveness of existing programmes is weak, of low quality [7–9] and rarely underpinned by behaviour change theory [10–11], thus limiting implementation in real world settings. We developed the Self-management of OA and chronic LBP through Activity and Skills (SOLAS) complex intervention, by adapting an existing efficacious intervention (Facilitating Activity and Self-management in Arthritis, FASA) [12] through an intervention mapping process [13]. SOLAS is underpinned by self-determination

theory (SDT), which proposes that people have basic psychological needs for autonomy, competence and relatedness, which if satisfied, for example, by the needs supportive communication style of a physiotherapist will increase individuals' autonomous motivation and engagement in health behaviours such as physical activity (PA) and self-management. SOLAS also targets other selected determinants of SM behaviour, including fear and pain catastrophizing in LBP patients [5, 14–16] via 31 evidence-based behaviour change techniques (BCTs), as illustrated in Figure 1. SOLAS is the first theory-driven, group-based intervention designed for a mixed group of people with OA and/or chronic LBP (CLBP). Therefore, as endorsed within the UK Medical Research Council guidelines, the credibility, acceptability and feasibility of this intervention warrants investigation prior to testing in a definitive trial [17].

# Aims and objectives

The aim of this cluster feasibility trial [ISRCTN49875385] was to evaluate the feasibility of providing the SOLAS intervention [experimental group] within a diverse range of primary care PT settings for patients with OA hip/ knee, lumbar spine and/or CLBP compared to usual individual physiotherapy (UP), which served as the pragmatic control group in order to inform its appropriateness for testing in a future definitive trial.

Based on key areas of focus for feasibility studies [18–21], our primary objectives were: (1) to assess the acceptability, demand and necessary adaptations of the SOLAS intervention to participants and physiotherapists in order to optimise its design, uptake and delivery; and (2) to determine the feasibility of trial recruitment, retention and follow-up procedures to inform the most efficient and effective study design for any future definitive trial. The secondary objectives were to explore the preliminary effects of the intervention on (3) physical function, pain, emotional and global wellbeing and (4) the process model of behaviour change compared to UP. This would inform any changes to the design of the SOLAS intervention for a future definitive trial.

A comprehensive assessment of the fidelity of intervention delivery, another key component of feasibility has been reported separately [22–24].

## Methods

# Design and Setting

This was an assessor-blinded multicentre two-arm parallel cluster randomised controlled feasibility trial comparing the SOLAS intervention to UP. A cluster randomisation was chosen for practical reasons and to prevent contamination by preference of patient or PT, with each primary, community and continuing care clinic (PCCC) serving as the cluster unit. The trial was conducted in publicly funded outpatient PCCC clinics in Ireland between September 2014 and June 2016. Ethical approval was granted by University College Dublin's Human Research Ethics Committee (LS–13–54), the protocol was approved by the

Health Service Executive (HSE) Primary Care Research Committee in March 2014, has been published [1] and registered in Current Controlled Trials [ISRCTN49875385].

# Cluster eligibility criteria, randomisation and allocation concealment

The PCCC clinic as the cluster was the unit of randomisation. The managers of eight primary care areas in Dublin/North Kildare, Ireland provided consent to the researchers for their clinic to participate and nominated 18 PCCC clinics for the trial that were screened for eligibility by the study team. Clinics were randomised on a 1:1 basis to provide either SOLAS (n = 9) or UP (n = 9) treatment, of which 14 proceeded to participate in the trial (7 per arm). Randomisation was conducted using a computerised random number generator algorithm by the statistician (RS) who was blinded to the study hypothesis. A researcher contacted all PT managers to inform them of their allocation arm. Prior to randomisation eligible PTs in all clusters were purposively selected by PT managers to participate in the trial based on affiliation with suitable study sites, interest, experience and caseload. The researcher provided all nominated PTs with a participant information leaflet and an opportunity to ask questions before obtaining written informed consent prior to cluster randomisation. Due to the nature of the intervention and the pragmatic cluster trial design it was not possible to blind PTs in either arm.

# Participant eligibility criteria

The participant recruitment procedure agreed with the clinics involved the Researcher (IJ) sending trial information and participant eligibility criteria (see Table 1) to all referring general practitioners, PTs raising awareness of the trial, screening waiting lists with the Physiotherapy Researchers (ET, AK) and sending potentially suitable referrals an invitation letter. Respondents were contacted by a Physiotherapy Researcher and provided with verbal information about the study, given an opportunity to ask questions and if interested provisionally screened for eligibility over the telephone. Interested and potentially eligible participants were then sent the participant information leaflet and invited to the local PCCC clinic. At the PCCC clinic written informed consent for data collection was obtained prior to face-to-face screening, PT assessment and participants completing the secondary outcome measures. The participants were then informed of their treatment allocation (based on the random allocation of the PCCC clinic) by the Physiotherapy Researcher.

## Insert Table 1 approximately here

# Trial interventions and physiotherapists

Treatment in both arms was provided by Chartered Physiotherapists from the participating PCCC clinics. Interventions pertain to both the cluster and individual participant level.

# SOLAS Intervention

## Training of Physiotherapists

PTs from seven clusters (n = 2 per site) randomised to the intervention arm attended 12 hours standardised training over two days in a Dublin metropolitan university within one month of their scheduled start date to deliver the SOLAS programme at their clinic. The training programme introduced PTs to the SOLAS intervention structure, content, support materials and delivery [1]. Its effectiveness in successfully supporting PTs to deliver SOLAS using a needs supportive communication style has been reported [22].

## Intervention

Participants were required to attend a 90-minute class for six consecutive weeks in the participating PCCC clinic or local community centre (if suitable gym facilities were not available) [1]. Each class comprised of 45 minutes education/group discussion on a specific SM topic and 45 minutes supervised group exercises. Participants were also provided with support materials to facilitate their engagement with the programme (e.g. handbook, pedometer). PTs recorded the dose of treatment provided in weekly treatment record forms (Table 2). Eleven trained PTs delivered SOLAS within the trial, with three PTs providing it on two occasions. PTs' high fidelity to the delivery of intervention content and support materials were reported previously [24].

## Usual individual physiotherapy

The UP treatment provided in seven randomised PCCC clinics was defined as individualised advice/education regarding PA, prescribed exercise, and lifestyle factors, exercise therapy and manual therapy at the PT's discretion. They were requested not to refer participants to group-based programmes for pain management during the trial. The content and dose of treatment provided were recorded by PTs (Table 2); there was no restriction on the number of visits. Thirteen PTs delivered treatment in the UP arm.

# Outcomes and data collection

The primary feasibility outcomes related to the acceptability, demand and necessary adaptations of the SOLAS intervention and the feasibility of trial recruitment, retention and follow-up procedures to participants and PTs were evaluated using a range of quantitative and qualitative methods (Table 2). The secondary outcomes were assessed using validated self-report measures of physical function, pain,

emotional and global wellbeing and a range of outcomes related to the process model of behaviour change. These measures were collected at baseline/start of treatment, 2 and 6 months from baseline/start of treatment, with an additional 6 week follow-up from baseline/start of treatment included for the behaviour change outcomes (see Additional file 1).

## Insert Table 2 approximately here

# Sample size

As specified in the trial protocol we aimed to recruit 12 to 14 clusters (PCCC clinics); a minimum of six clusters in each arm participating in two waves of recruitment with the aim to recruit at least six participants in each cluster per wave resulting in 144 participants (72 per arm) [1]. This sample size would also meet recommendations for feasibility studies that 30 participants are required per arm in order to estimate parameters for future sample size calculations. Accounting for the cluster design effect and assuming an intraclass correlation coefficient (ICC) of 0.03 required 36 participants per arm, and allowing for 25% loss to follow up, we aimed to recruit 48 participants per arm (96 in total).

The specific a priori feasibility criteria to move to a definitive trial were that:

- the SOLAS intervention was acceptable to participants and PTs and necessary adaptations are achievable
- it was feasible to deliver the intervention with high fidelity
- the recruitment targets of 12 clusters, a cluster size of six and a sample size of 144 participants were achieved
- the recruitment, retention and screening procedures were successful in identifying the target population and workable for a larger trial
- the outcome measures and follow-up procedures were acceptable to participants and operational in a larger trial
- there was evidence of preliminary effects of the intervention on secondary outcomes and the theoretical process model of behaviour change

# Data analysis

Statistical analysis was by intention to treat according to participants' cluster allocation. Quantitative data were coded and entered into the Statistical Package for the Social Sciences (IBM SPSS Statistics Version 24). Since this was a feasibility trial a priori descriptive analysis of the quantitative and qualitative data were undertaken to answer the primary feasibility objectives [1]. Both participant and PT interviews were transcribed, anonymised (ET, IJ), and analysed (DMA, DH, JM) using an inductive thematic approach (see Additional file 2) [25]. Analysis of the primary feasibility objective related to trial

procedures were undertaken on an interim basis after each study wave by the research team and used to inform minor protocol refinements for subsequent waves as outlined in Table 2. Analysis of the secondary outcome measures was undertaken at the end of the trial and performed by the statistician (RS) who remained blinded to group identification until analysis was complete. A linear mixed model was used to examine change over time in participant outcomes between treatment groups, while adjusting for study waves and clusters. Three-level logistic or linear mixed effects models were fitted, with a random intercept for each participant, and a random intercept for each cluster as a higher-level effect. Time and group effects, and an interaction term for Time by group were included in each model. Treatment effects were reported as model estimated marginal means with 95% confidence intervals (CI) or as medians, 1st and 3rd quartile, if skewed or a substantial floor or ceiling effect was observed. ICCs for the clusters were calculated for each endpoint. Due to the multi-joint inclusion of participants further exploratory analysis of the change over time in secondary outcomes within each diagnostic subgroup was undertaken. Estimated marginal means (or medians) are also reported for each group at each time-point and mean changes from baseline to subsequent time-points are reported within groups, and between-group differences at each time-point. From logistic models odds ratios for change from baseline to each subsequent time-point, and ratios of odds ratios to contrast the groups are reported.

## Results

# Recruitment

Details of cluster and participant recruitment and retention are shown in Figure 2. In January 2014, 20 clusters were invited, 18 were eligible and randomised, of which 14 proceeded to participate in the trial (7 per trial arm). Each cluster participated in two waves of recruitment (four clusters participated in pilot study) resulting in three study waves (W1-W3). In total, 120 participants (83.3%; of n = 144 expected) were recruited (Intervention n = 59; UP n = 61). The number of clusters and the number of participants recruited in each study wave are detailed in Table 3. Overall, the average cluster size was below the target of six participants (Intervention: mean (SD) = 4.92 (1.31), range 2–7; UP: mean (SD) = 5.08 (2.43), range 1–9). Three of 7 sites in the Intervention arm had a cluster size of at least six participants compared to 5 of 7 sites in the UP arm. The recruitment rate in W1 was below target, which resulted in the addition of two contingency clusters for W2 and W3 and minor changes to the recruitment protocol which resulted in an increase in the recruitment rate and cluster size.

## Insert Figure 2 and Table 3 approximately here

Between September 2014 and November 2015, 1708 referrals were identified by PTs, with 1136 (66.5%) excluded predominantly due to diagnosis (n = 784), age (n = 158), symptom duration (n = 53) and exclusion criteria (n = 133; Figure 2). 572 invitation letters were sent to potentially eligible participants, of which 375 (65.6%) responded, 224 (59.7%) were excluded by telephone screen mainly due to preference for individual PT (n = 62), inability to attend SOLAS group (n = 30), physiotherapy in past 6 months (n =

22) or poor English (n = 31). Of the 151 invited to face-to-face screening, 31 (20.5%) were excluded (nerve root compromise n = 9, non-attendance n = 12), with 120 consenting participants recruited, representing 20.9% of invitation letters and 7% of total referrals.

# Treatment, attendance and satisfaction

The majority of participants received treatment as allocated (Intervention n = 49; UP n = 54), 16 did not receive any treatment (Intervention n–9; UP n = 7), and one participant randomised to the Intervention arm requested and received individual physiotherapy but remained in the Intervention arm for the ITT analysis. The mean (SD) number of treatments received in each arm was comparable (Intervention: 4.3 (1.6); UP: 3.8 (1.7), however, the mean (SD) duration of treatment was longer in the UP arm (7.8 (3.8) weeks) compared to the Intervention arm (4.8 (1.6)). Participants in both arms reported positive ratings for overall physiotherapy care received (Table 4).

## Insert Table 4 approximately here

PT characteristics were similar between arms (see Additional file 3). The SOLAS intervention was delivered 12 times across all seven randomised clusters (five of the seven delivered it twice), in four PCCC clinics and three local community centres/gyms (see Additional file 4). Only two sites reached the target class size of 6 participants, with the mean class size of 4.1 (1.2) participants (min-max:2–6). Eleven of 49 participants dropped out during the Intervention for various reasons, but the majority of participants (57.2%, n = 28) attended at least five classes corresponding to 83.3% adherence and had a treatment duration of six weeks (n = 27, 55.1%). All UP treatments were provided within all seven randomised PCCC clinics; details of treatment provided are in Additional file 5.

# Follow-up procedures

Between October 2014 and June 2016 follow up data were obtained from 80.8% (n = 97) of participants at 6 weeks, 84.2% (n = 101) at 2 months and 71.7% (n = 86) at 6 months. The majority of respondents completed follow-up by phone (see Additional file 6), with the mean (SD) completion time increasing at each time-point [6 weeks: 24 (5.2) minutes (min-max:15–35); 2 months: 41 (8.9) minutes (20–60); 6 months: 44 (8.8) minutes (min-max:25–60) as questionnaire length also increased. The majority of 6-month respondents found the follow-up procedures acceptable (Table 4). There was minimal missing data and no measure that participants reported difficulty completing.

# Qualitative Interviews

Twelve participants who had received the Intervention (8F, 4M; median (min-max) age years = 64.5, 40–79) were interviewed; Those interviewed had attended a median (IQR; min-max) of six sessions (1.8; 1–6).

Ten of the 11 PTs who had delivered the Intervention were interviewed. The main findings from the qualitative interviews related to the primary feasibility objectives. These ranged from the acceptability and demand of the Intervention from the participant and PT perspectives, as well as the practicality and necessary adaptations to the intervention, PT training programme and trial recruitment procedures for a future definitive trial. A synopsis of these findings is presented below and supported by exemplar quotes and the number of individuals reporting each theme in Additional file 2. The qualitative studies are reported in accordance with current guidelines [26] (see Additional file 7).

# SOLAS Intervention

## Acceptability

Participants viewed the overall experience of engaging with the intervention and resource materials very positively and had a good understanding that it was designed to educate them to take a more active role in managing their chronic musculoskeletal condition. The social aspect of the group was viewed as a key benefit by many participants. Similarly, PTs were overtly positive about their experience of providing the intervention to a mixed group, reporting it acceptable and feasible to deliver during the trial and that it addressed a need within their service and would have relevance for clients with other musculoskeletal disorders.

## Demand

Participants reported they were likely to use some or all of the SM behaviours and related components in their daily lives, however, some participants found goal setting difficult to utilise. Key PT demands during SOLAS delivery included the volume of educational content during the first session, the perceived overemphasis on goal setting, and striking a balance in their use of language that provided appropriate direction to participants while adhering to the principle of autonomy support. Other challenges included delivering the intervention to a small group and those with inconsistent attendance or lacking motivation to engage in the exercise programme.

## Practicality

Despite variations in facilities, gym and audio-visual equipment, PTs were satisfied that there were no practical difficulties with intervention delivery. The recruitment of sufficient participants was highlighted as a key issue that would need to be addressed for a future definitive trial, with the majority of PTs believing a class size of six was optimal.

## Adaptation

Minimal changes were made during delivery but a number of PTs made suggestions for future adaptations, particularly decreasing the educational content in session one, potentially reducing the duration of the education component to 20–25 minutes, delivering the exercise component first and simplifying and adding more visuals to the handbook for those with lower literacy levels and limited time to read the materials provided.

# Physiotherapist Training

All PTs were positive about the training and feedback provided in preparation for intervention delivery, considering it acceptable in improving their ability to promote SM, while also suggesting more specific guidance and practical examples to support the demand and increase their confidence in the use of autonomy supportive language within a group setting would be beneficial in future training.

# Trial recruitment procedures

Participants and PTs spoke very positively about their experience of trial participation. PTs expressed some concerns about the enrolment of some participants due to high levels of pain, the strict exclusion criteria and small catchment areas that limited recruitment numbers, proposing over-recruitment and the provision of some pre-group individualised treatment for a definitive trial to increase uptake.

# Secondary outcome measures and behavioural process outcomes

Participants' baseline sociodemographic and clinical characteristics were comparable between groups (Table 5). There were a higher proportion of participants with a single area of pain (74.1%) than multi-joint pain (25.9%), with CLBP being the most prevalent diagnosis followed by OA knee. Both the Intervention and UP arms were considered credible with similar treatment expectations.

Participant's baseline secondary outcome and behavioural process outcome scores were comparable (Table 6). The results of linear mixed model analysis for the continuous and categorical variables are provided in Tables 6 and 7 respectively, Table 8 details the mean within and between group changes from baseline, while further exploratory analyses of selected outcomes according to joint pain diagnosis is detailed in Additional file 8.

## Insert Tables 5–8 approximately here

# Changes in secondary outcomes

There were improvements in the mean scores for most secondary outcomes at 2 and 6 months for the overall sample and within each diagnostic subgroup, apart from the WOMAC scores which showed minimal change for both OA hip and knee participants. There were small between group mean differences, apart from the NRS-pain intensity at 2 months and RMDQ at 6 months which approached their MCID values in favour of the UP group. However, the proportion of responders [≥30% drop from baseline] at 2 months was comparable in both groups for the RMDQ [UP: 57.6%; SOLAS: 58.7%] and NRS-pain intensity scale [UP: 47.1%; SOLAS: 44%].

# Changes in the process model of behavioural change

At 6 weeks, there were improvements in the SDT-based determinants of SM behaviour with the between group mean difference in change from baseline in favour of SOLAS for the measures of perceived competence [PCQ-physical activity mean, 95% CI: = −0.37, −0.99, 0.25; PCQ-SM = −0.46, −1.07, 0.16], and motivation to participate in physical activity [BREQ-RAI = −0.71, −1.78, 0.36] and to self-manage [TSRQ-RAI = −1.19, −2.96 to 0.59]. There were also small changes at 6 weeks in favour of SOLAS for pain catastrophizing [PCS = −1.02; −2.96, 5.00], but in favour of UP for fear (TSK = −0.71, −1.99, 0.56). At 2 and 6 months, the intervention effects on perceived competence and autonomous motivation gradually reduced, while the effects on controlled and amotivation remained stable or increased with small between group differences in favour of SOLAS at 6 months. Changes in pain catastrophizing and fear increased in both groups over time, with small between group mean differences evident (Table 8).

There was an increase from baseline in both groups in the proportion of participants engaging in moderate or high levels of PA and SM behaviours related to physical activity at all time-points with the group ratio of ORs favouring SOLAS at all time-points. There was an increase in the proportion of participants using mental relaxation techniques only in the SOLAS group with large group ratios of ORs at 6 weeks (4.34) and 2 months (4.39), while the non-use of pain relief increased at 6 weeks in both groups and continued to rise in the UP group only, the group ratio of ORs were small at all time-points. Finally, there were large increases in the proportion of participants who reported eating healthily at all time points in both groups.

## Discussion

This is the first feasibility trial of a group-based theoretically informed complex self-management intervention for both OA and chronic LBP that has evaluated its acceptability alongside testing the proposed trial procedures from the perspectives of both healthcare providers and patients. Preliminary effects of the intervention were also explored, as was the proposed process model of behaviour change.

# Feasibility: Acceptability, demand and necessary adaptations of the SOLAS intervention

The findings of the qualitative interviews and self-report measures demonstrated that the SOLAS intervention content, support materials, and group-based mode of delivery were acceptable and appropriate to participants with OA and CLBP and physiotherapists alike. These findings are reinforced by our previous report of high fidelity to these elements of the intervention [24]. Feasible adaptations for a future definitive trial include simplifying the education content of the first session to increase its acceptability and fidelity and ensuring the materials are suitable for participants with low health literacy.

Fifty seven percent of participants attended five out of six SOLAS classes. This is a higher attendance rate than other RCTs of 6-week group interventions for CLBP delivered in the Irish health service [27–28], and comparable to a large cluster trial of the ESCAPE intervention for OA knee in the UK health service [29]. However, the small class sizes and inconsistent participant attendance placed a demand on PTs' ability to deliver the intervention, and also challenges the viability of a future definitive trial of this intervention, as discussed below.

# Feasibility: Trial recruitment, retention and follow-up procedures

The trial was successful in recruiting 14 clusters demonstrating the strong partnership between the research team and PCCC areas established during the development phase [13]. Overall, 21% of those sent invitation letters were recruited, which is within the range of other trials of group-based programmes for these populations [27, 29–31]. Furthermore, the recruitment protocol successfully enrolled participants with OA of the hip, knee, lumbar spine and CLBP, with the latter being the most prevalent in line with population data. In contrast to the FASA intervention, which restricted recruitment to individuals with OA aged at least 50 years [12], our findings have demonstrated the feasibility of enrolling and retaining younger participants with CLBP to a group-based programme alongside older people with OA. Nonetheless, the average cluster size of five participants in both arms and the overall recruitment rate were below target. The recruitment protocol for the trial was embedded within the health system and developed in partnership with PTs [13]. However, participant recruitment was outside routine practice and despite increases in the recruitment rate, cluster size and response to invitation letters across waves as procedures were improved additional refinements are needed for any future definitive trial to ensure recruitment targets are achievable. For example, the time-consuming paper-based exclusion of most referrals due to diagnosis and age is not an effective use of trial resources or feasible for a large-scale definitive trial and would be enhanced if computer-generated identification codes were available in Ireland's health service as in other jurisdictions. Since the completion of this trial, the importance of patient and public involvement (PPI) in research has become increasingly recognised in Ireland [32–33]. The development of a recruitment pathway for a definitive trial would warrant further PPI engagement to address barriers and optimise enablers to participation in the group-based class arm in particular [34].

The response rate at 2 months was acceptable but the 6 month response rate at 72% was below the assumed loss to follow-up rate of 25%. It is likely that despite the support of our Researcher the average

41 minutes to complete telephone follow-up at 2-months and the addition of the CSRI at 6 months were off putting to some non-respondents, notwithstanding the reported acceptability and lack of burden reported by the majority of responders. Therefore, the number of follow-up points and multiple outcome measures that accounted for each joint condition and the complex behaviour change process would need to be reduced to maximise response rates and optimise follow-up procedures for a future definitive trial as discussed below.

# Changes in secondary outcomes

The finding of comparable small effects for both SOLAS and individual PT for the majority of secondary outcomes is consistent with our rapid review [9] and other systematic reviews of education and exercise SM programmes for OA [7] and LBP [8]. The larger improvements in pain intensity in the UP group at 2 months and in LBP-related functional disability at 6 months could be associated with the multi-modal treatments utilised targeting analgesia, including clinical guideline endorsed manual therapy [5]. A recent trial of SDT-driven individual physiotherapy for LBP found limited effects for pain, function or quality of life compared to usual PT, with similar group differences to the current study [35]. The minimal change in the WOMAC-physical function subscale for OA hip or knee participants may reflect its poor responsiveness compared to other measures or physical performance tests and warrants omission in any future definitive trial [36], with the use of only the SF–12 for all diagnostic subgroups to further reduce respondent burden.

The SOLAS intervention maximal dose of nine hours over 6 weeks, which was agreed with PTs during the development phase and found to be acceptable in this feasibility trial, is relatively low compared to other group-based interventions (including FASA) that have shown larger between and within group effects on pain, function and quality of life outcomes for OA knee [29, 37–38]. Conversely, clinical LBP guidelines recommend group-based exercise programmes that promote self-management but were unable to recommend the intensity of the programme [5].

# SOLAS process model of behaviour change

The effect of the intervention on LBP-related determinants was minimal, with weak effects in the full sample for pain catastrophizing and no effect on fear at completion of the 6-week programme [5, 39]. The measurement of fear avoidance may have been underestimated due to the use of the 6-item activity avoidance subscale of the TSK 11 [40] to reduce respondent burden. Nonetheless, it is proposed that these variables should be removed from the process map of behaviour change given their tentative evidence, its complexity and the multi-joint focus of the intervention.

In line with the assumptions of SDT, there were small changes in participants' perceived competence and motivation for both PA and self-management that favoured SOLAS at week six, but these changes alone were not enough to promote long term increases in participant behaviour. These findings are consistent

with previous literature and suggest sustained increases in autonomous motivation may be required for behaviour change [41]. Although PTs underwent training and were deemed competent to deliver SOLAS within the feasibility trial, they struggled to effectively utilise specific strategies related to goal setting [22–23]. This is noteworthy as a collaborative goal-setting process between a health care professional and patient is likely to be important in increasing and sustaining a patient's autonomous motivation and competence for the particular behaviour [43–45]. Additionally, some PTs in the qualitative interviews felt they needed further training to augment their use of autonomy supportive language (i.e., flexible and suggestive rather than pressurising language) when delivering SOLAS, an important communication technique for promoting autonomous motivation [46]. This requirement was reinforced by independent observers who rated PTs' average use of autonomy supportive language as moderate (4.2 on a 7-point Likert scale) [22].

The small increases found in subjectively measured PA and in the SM behaviours related to PA within the Intervention up to 2 months provide preliminary evidence of its effect on these behaviours. PTs overall moderate fidelity to the intervention BCTs and their inability to deliver all 26 BCTs targeting PA within the trial may have contributed to these small effects [23]. If a definitive trial is to take place, first, the core intervention BCTs must be identified and second, training enhancements are required to target PTs' use of particular BCTs.

The limitation of self-report measures of PA is well recognised in the literature, due to recall bias, social desirability bias and poor correlation with objective measures [47]. There is currently no evidence that an increase in self-reported PA is associated with improvements in pain and disability outcomes for OA [47] and LBP [48], but the quality of current research is low, the majority of current interventions lack a strong theoretical basis and have failed to evaluate treatment fidelity and the findings of the current study shed some light on these elements for future interventions targeting PA.

The higher use of mental relaxation techniques in the SOLAS group at 2 and 6 months may reflect the greater focus on the uptake of these skills within the Intervention, and may be associated with the consistent small reductions in HADS subscale scores in favour of SOLAS, suggesting the relatively short time focusing on this SM skill could be increased given the moderate levels of anxiety and depression of the sample at baseline. Conversely, the marginally lower use of pain relief techniques in the UP group at 2 and 6 months could be related to the greater reduction in pain intensity at 2 months in this group.

The major strengths of this feasibility trial relate to the use of a comprehensive range of quantitative and qualitative methods and the inclusion of a high number of clusters across a range of sites and geographical areas to address clearly defined feasibility objectives and a priori criteria for moving to a definitive trial from both participant and PT perspectives. The design of the feasibility trial was guided by the MRC framework, underpinned by behaviour change theory and extensive stakeholder engagement, and its reporting conforms to CONSORT guidelines for feasibility [21] and cluster trials [49] (see Additional file 9). There were also some limitations that should be acknowledged including the below target recruitment rate and the high number of secondary outcomes that probably contributed to the

below expected response rate at 6 months. While adherence to the intervention SM skills (apart from specific exercise) were measured by an unvalidated researcher-designed questionnaire, consistent with many similar studies [50], the qualitative participant interviews of participants enactment of SM skills supported these findings and could contribute to its future validation. A self-report measure was used to assess participant PA, the inclusion of a user-friendly low-cost objective measure of PA in any future definitive trial is warranted. It was not possible to blind participants or PTs due to the nature of the study and we did not interview participants who did not complete the 6-month follow-up or those with low attendance rates.

## Conclusions

The findings have demonstrated that the complex, group-based, theory-driven SOLAS intervention is acceptable to PTs and patients with OA and CLBP and has preliminary evidence of small effects on the secondary outcomes and the process map of behaviour change comparable to individual physiotherapy in its current format and dose. Minor changes to the intervention content, underpinning process model, BCTs and PT training programme have been identified to optimise its design, uptake and delivery for evaluation in a definitive trial. However, the likelihood of recruiting enough participants for a definitive trial in Ireland's current primary care service is challenging given the significant constraints on participant identification, recruitment and enrolment procedures identified in this study.

## Declarations

# Ethics approval and consent to participate

Central ethical approval was granted by University College Dublin's Human Research Ethics Committee (LS–13–54) which granted ethical approval to recruit at local centres. Following receipt of this ethical approval the protocol was approved by the Health Service Executive Primary Care Research Committee to conduct the trial in all local centres. We did not begin recruiting at local centres in the trial until local approval for the trial was obtained from the Health Service Executive Primary Care Research Committee in March 2014. All study participants gave written informed consent to participate.

# Consent for publication

Not applicable

# Availability of data and material

All data generated and analysed during this study are included in the published article and its supplementary information files.

# Competing interests

The authors declare that they have no competing interests.

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# Authors contributions

DH contributed to the conception and design of the study, obtained funding, led the data collection process by the trial team, contributed to the analysis of the quantitative feasibility data, participant and physiotherapist interviews and the interpretation of all data, drafted and critically revised the manuscript. IJ managed the feasibility trial and contributed to the data collection, analysis and interpretation of participant recruitment, follow-up and secondary outcome data, and the transcription of interviews and helped to draft the manuscript. AMH contributed to the conception and design of the study and the acquisition of funding and helped to critically revise the manuscript. AK contributed to data collection during participant recruitment and SOLAS intervention delivery, evaluated the effectiveness of the physiotherapist training programme and physiotherapist fidelity to the delivery of the SOLAS intervention theoretical components and helped to critically revise the manuscript. ET contributed to data collection during participant recruitment and SOLAS intervention delivery, conducted the participant interviews and contributed to their analysis, evaluated physiotherapist fidelity to delivery of the SOLAS intervention content and support materials and helped to critically revise the manuscript. DMA contributed to the analysis of the physiotherapist and participant interviews and helped to draft the manuscript. CL contributed to the design of the study, the interpretation of data and helped to critically revise the manuscript. SMcD contributed to the design of the study, the interpretation of data and helped to critically revise the manuscript. SG contributed to the design, data collection and analysis of the physiotherapist interviews, and interpretation of the resultant data and helped to critically revise the manuscript. RS contributed to the design of the feasibility trial, conducted the cluster randomisation, analysed the secondary outcomes, contributed to the interpretation of the resultant data, and helped to draft and critically revise the manuscript. JM contributed to the design of the feasibility trial, the analysis of the physiotherapist interviews and interpretation of all data and helped to draft and critically revise the manuscript. All authors read and approved the final manuscript.

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# Additional files

The datasets supporting the conclusions of this article are included within the article and its additional files.

Additional file 1: Secondary Outcomes and Process Model of Behaviour Change Measures

Additional file 2: Qualitative Interview Methods and Results

Additional file 3: Physiotherapist Baseline Characteristics

Additional file 4: SOLAS Intervention Sites, Physiotherapists and Participants

Additional file 5: Usual Physiotherapy Treatment

Additional file 6: Methods of Follow-up

Additional file 7: Consolidated Criteria for Reporting Qualitative Research (COREQ) Guidelines for Physiotherapist and Participant interviews

Additional file 8: Exploratory Analysis by Joint Pain Condition

Additional file 9: CONSORT Checklist

Figure 1 Process model of behaviour change in SOLAS intervention

Figure 2 CONSORT flow chart edited for cluster and feasibility trials

# List Of Abbreviations

BCT: Behaviour change technique, BREQ: Behaviour Regulation Exercise Questionnaire, CI: Confidence interval, CSRI: Client Services Receipt Inventory, CLBP: Chronic low back pain, EQ–5D: EuroQol 5-D Weighted Health Index, FASA: Facilitating Activity and Self-management in Arthritis, GPE: Global Perceived Effect Scale, HADS: Hospital Anxiety and Depression Scale, ICC: Intraclass correlation coefficient, IPAQ: International Physical Activity Questionnaire, MRC: Medical Research Council, NRS: Numeric Rating Scale, OA: Osteoarthritis, PA: Physical activity, PCCC: Primary, Community and Continuing Care, PCQ-PA: Perceived Competence Questionnaire for physical activity, PCQ-SM: Perceived Competence Questionnaire for self-management, PCS: Pain Catastrophizing Scale, PPI: Patient and public

involvement, PT: Physiotherapy, RMDQ: Roland Morris Disability Questionnaire, SDT: Self-determination theory, SF–12 PCS: Short Form–12 Physical Component Score, SM: Self-management, SOLAS: Self-management of osteoarthritis and low back pain through activity and skills, SMBQ: Self-management Behaviour Questionnaire, TSRQ: Treatment Self-Regulation Questionnaire, TSK–11: Tampa Scale of Kinesiophobia Activity Avoidance Subscale, UP: Usual individual physiotherapy. W: Wave, Western Ontario and McMaster Universities Arthritis Index: WOMAC.

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# Tables

### Table 1. Eligibility criteria for the feasibility trial

| ***Inclusion criteria*** | |
|---|---|
| Diagnosis | ***Osteoarthritis***<br><br>NICE [4] working diagnosis of osteoarthritis of the hip, knee or lumbar spine defined as:<br><br>· Age 45 years old or over, and<br><br>· Activity related joint pain and<br><br>· Either no morning joint-related stiffness or morning stiffness that lasts no longer than 30 minutes<br><br>***Non-specific Low Back Pain***<br><br>≥ 30 years low back pain with non-specific low back pain of mechanical origin with or without radiation to the lower limb |
| Symptom duration | Chronic (≥3 months) |
| English language | Be able to read, understand and speak English without assistance |
| Contact status<br><br>Availability | Access to a telephone for screening and assessment<br><br>Available to attend a 6 week start stop group class of 1.5hrs per week |

| *Exclusion criteria* | |
|---|---|
| Pathology | Suspected or confirmed serious spinal pathology (fracture, metastatic, inflammatory or infective diseases of the spine, cauda equina syndrome/widespread neurological disorder) |
| | Nerve root compromise (2 of strength, reflex or sensation affected for same nerve root) |
| | Lower limb arthroplasty |
| Past medical history | Spinal surgery or history of systemic / inflammatory disease |
| Current medical status | Scheduled for major surgery during treatment |
| Contraindications | Unstable angina / uncontrolled cardiac dysrhythmias / severe aortic stenosis / acute systemic infection accompanied by fever |
| Other | No confounding conditions, such as a neurological disorder, intellectual disorder or unstable psychiatric condition.<br><br>Bladder or bowel incontinence<br><br>People who are assessed to be at high risk of falls<br><br>Physiotherapy in the preceding 6 months<br><br>Unable or unwilling to attend<br><br>Ongoing litigation related to the pain condition |

## Table 2. Primary Feasibility Outcomes and Measures

| Feasibility Outcome | Variable | Measure and items | Details | Measurement point, trial arms |
|---|---|---|---|---|
| *Acceptability, demand and necessary adaptations of the SOLAS intervention and trial design and procedures* | Expectation of treatment<br><br>[Participants and PTs] | Expectation of treatment scale<br><br>4-items<br><br>10 point numeric rating scales ranging from 'not at all helpful' to 'extremely helpful'. | Participants and PTs rate how helpful they believe both the SOLAS intervention and usual individual PT treatment will be for people with OA and CLBP. | Baseline only |
| | Satisfaction with outcome and care<br><br>[Participants] | Satisfaction questionnaire*<br><br>2-items<br><br>Measured using 5-point numeric rating scales. | Participants rate their satisfaction with PT care received in the trial. | 2 months,<br><br>6 months |
| | Acceptability of trial procedures<br><br>[Participants] | Brief questionnaire developed for this trial*<br><br>11-items<br><br>Measured using 5-point numeric rating scales and yes/no responses. | Participants rate their acceptability *and perceived burden of outcome measure completion.*~ | 6 months |
| | Attendance rate at weekly SOLAS intervention class<br><br>[Participants] | Treatment record form<br><br>developed for this trial [24] | SOLAS intervention PTs completed weekly treatment record forms which captured participant attendance, rates and reasons for non-attendance or early withdrawal | During SOLAS intervention delivery |
| | Individual qualitative interviews<br><br>[Participants] | Purposive sample of participants who received the SOLAS intervention invited to participate in individual qualitative semi-structured telephone interviews with Physiotherapy Researcher | Participants discussed their experience of the SOLAS intervention and *trial participation* and necessary adaptations to optimise acceptability and uptake | Post completion of 6 month follow-up |
| | Individual qualitative interviews | All PTs who delivered the SOLAS intervention invited to participate in individual qualitative | PTs' discussed their experience of delivering the SOLAS intervention, PT | Within two weeks of completion of SOLAS |

| | | | | |
|---|---|---|---|---|
| | [PTs] | semi-structured telephone interviews with Qualitative Researcher | training programme and *trial recruitment procedures* and necessary adaptations to optimise acceptability and uptake | intervention delivery |
| *Feasibility of trial procedures* | Recruitment rates | Cluster recruitment | Calculation of recruitment rate and comparison to trial protocol: minimum of 6 clusters per arm participating in two waves of recruitment | |
| | | Participant recruitment | Calculation of participant recruitment per study arm, per cluster and overall and comparison to trial protocol: 6 participants in each cluster per wave [i.e. 144 participants, 72 per arm] | |
| | Retention rate | Reasons for withdrawal | Trial protocol specified retention of 36 participants per arm. Assess number and reasons for withdrawal | |
| | Refusal rate | Reasons for refusal | Assess number and reasons for refusal and if they can be addressed for definitive trial | |
| | Eligibility criteria | Suitability | Assess number and reasons for exclusion at each stage in the screening process and if any changes needed for definitive trial | |
| | Screening process | Success and practicality | Trial protocol specified three stage screening of waiting list, telephone and face-to-face screening involving PTs and Researchers. Assess if any changes needed for definitive trial | |
| | Follow-up procedures | Response rate<br><br>Methods of follow-up | Trial protocol specified 25% loss of follow-up overall | |

| | |
|---|---|
| Time to complete telephone follow-up | Proportion of participants completing phone, post or email follow-up |
| Level of missing data | |
| Participant burden | Researcher time to administer outcome measure completion recorded at each follow-up point |
| | Missing data for all measures recorded by the Researcher |
| | Acceptability of follow-up procedures |

## Table 3. Cluster size by study wave, site and treatment arm

| | SOLAS Intervention | | | Usual Physiotherapy | | |
|---|---|---|---|---|---|---|
| **Wave** | **Site code** | **Target recruitment** | **Cluster size recruited** | **Site code** | **Target recruitment** | **Cluster size recruited** |
| **W1** | A* | 6 | 2 | H | 6 | 3 |
| Autumn 2014- | B | 6 | 6 | I* | 6 | 7 |
| Spring | C | 6 | 4 | J* | 6 | 6 |
| 2015 | D | 6 | 5 | K | 6 | 3 |
| | | | | L | 6 | 3 |
| **Total** | 4 | 24 | 17 | 5 | 30 | 22 |
| **Mean (SD)** | | | 4.25 (1.71) | | | 4.40 (1.95) |
| **W2** | B | 6 | 4 | H | 6 | 4 |
| Spring-Autumn 2015 | C | 6 | 5 | K | 6 | 4 |
| | D | 6 | 4 | L | 6 | 7 |
| | E* | 6 | 7 | M | 6 | 6 |
| | F | 6 | 6 | N | 6 | 8 |
| | G | 6 | 5 | | | |
| **Total** | 6 | 36 | 31 | 5 | 30 | 29 |
| **Mean (SD)** | | | 5.17 (1.17) | | | 5.80 (1.79) |
| **W3** | F | 6 | 6 | M | 6 | 1 |
| Autumn 2015- | G | 6 | 5 | N | 6 | 9 |
| Spring 2016 | | | | | | |
| | 2 | 12 | 11 | 2 | 12 | 10 |
| **Mean (SD)** | | | 5.50 (0.71) | | | 5.00 (5.66) |
| **Total** | 7 | 72 | 59 | 7 | 72 | 61 |

*Pilot study sites

**Table 4. Participant satisfaction and acceptability of follow-up procedures at 6-month follow-up**

Due to technical limitations, Table 4 is only available as a download in the supplemental files section.

**Table 5. Baseline sociodemographic variables**

Due to technical limitations, Table 5 is only available as a download in the supplemental files section.

**Table 6. Model-predicted mean (95% CI) outcomes per group over time.**

Due to technical limitations, Table 6 is only available as a download in the supplemental files section.

**Table 7. Percentages for categorical outcomes**

Due to technical limitations, Table 7 is only available as a download in the supplemental files section.

**Table 8. Mean (95% CI) within and between group changes**

Due to technical limitations, Table 8 is only available as a download in the supplemental files section.

# Figures

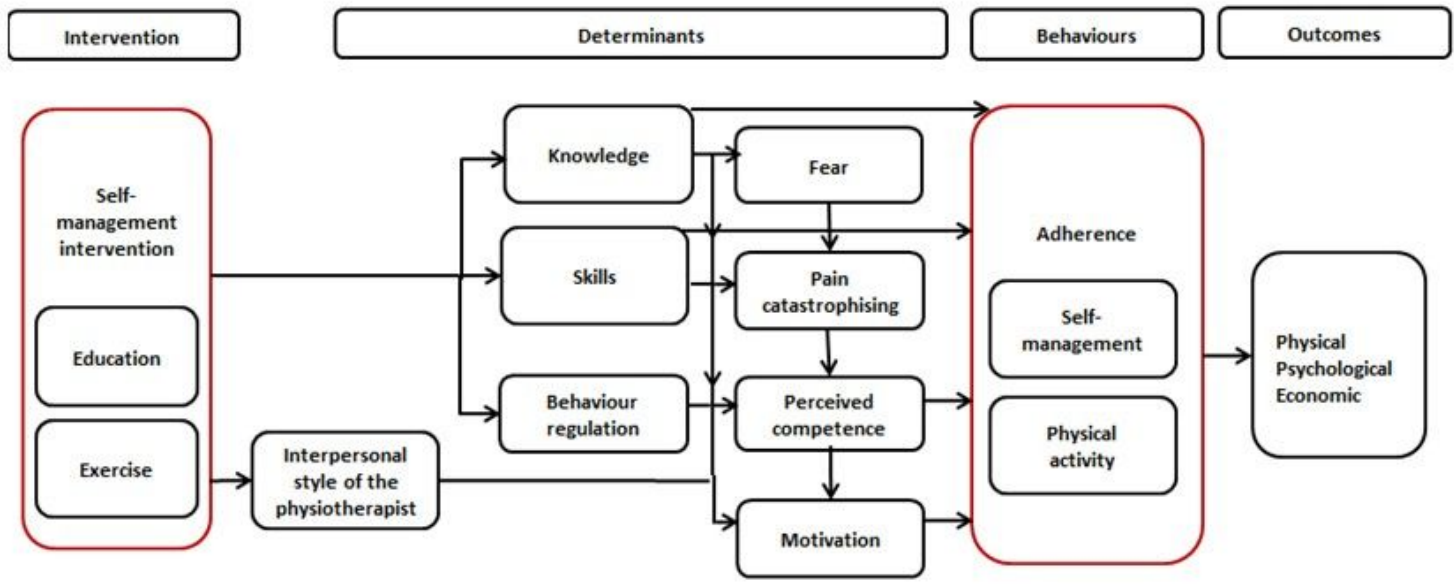


**Figure 1**

Process model of behaviour change in SOLAS intervention

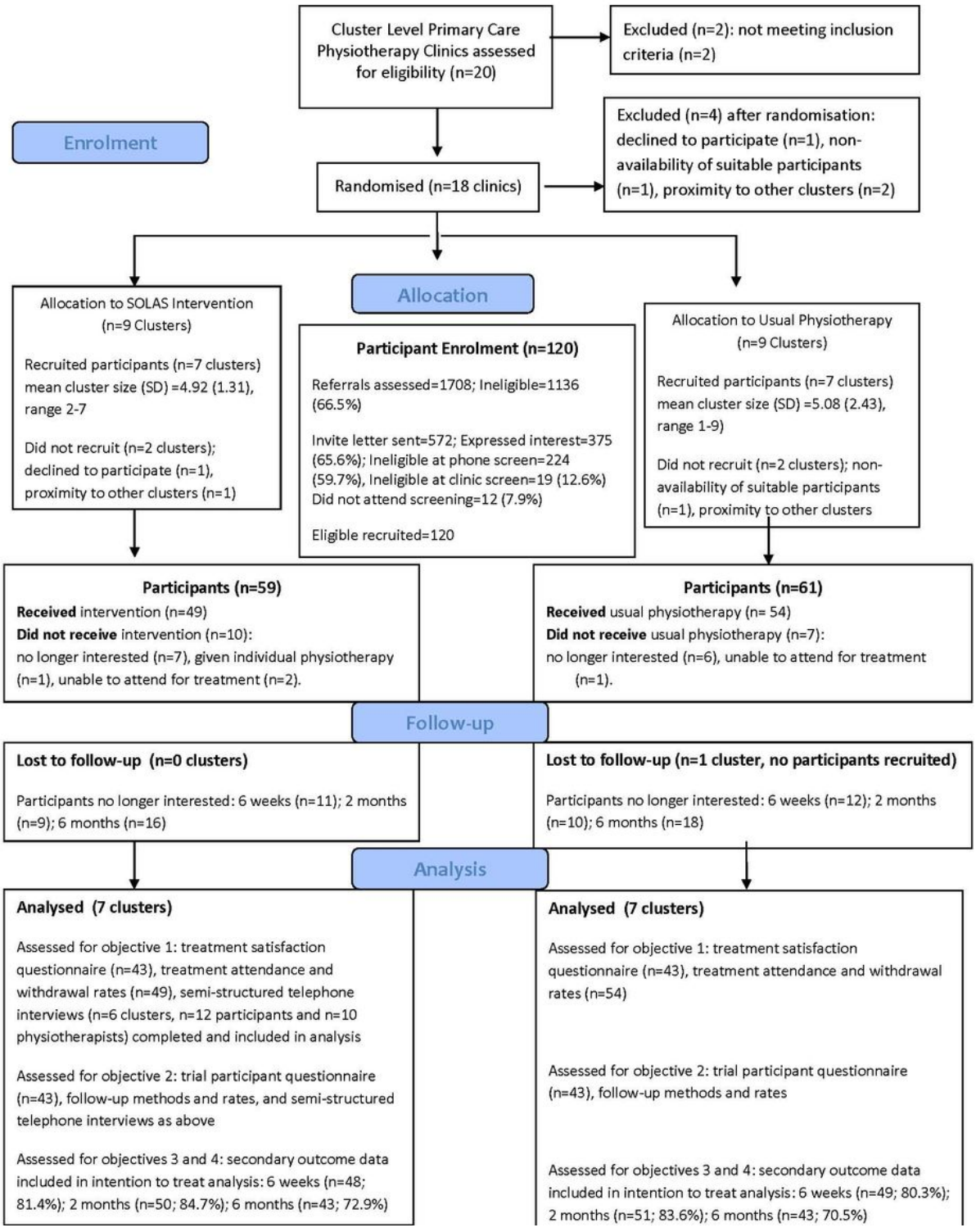


**Figure 2**

CONSORT flow chart edited for cluster and feasibility trials

# Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- supplement1.pdf
- supplement2.docx
- supplement3.docx
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