AMJ Australasian Medical Journal [AMJ 2016;9(9):297–307]

Efficacy of the Flinders chronic condition management program in obese patients with hip or knee osteoarthritis: A study rationale and protocol

Ladan Sahafi[1,2,3], David Smith[1], Kristen Georgiou[2], Jegan Krishnan[2,3], and Malcolm Battersby[1]

1. Flinders Human Behaviour and Health Research Unit, Flinders University, Australia
2. Department of Orthopaedics, Flinders University, Australia
3. International Musculoskeletal Research Institute, Australia

RESEARCH

Please cite this paper as: Sahafi L, Smith D, Georgiou K, Krishnan J, Battersby M. Efficacy of the Flinders chronic condition management program in obese patients with hip or knee osteoarthritis: A study rationale and protocol. AMJ 2016;9(9):297–307.
http://doi.org/10.21767/AMJ.2016.2658

Corresponding Author:
Ladan Sahafi
Flinders Human Behaviour and Health Research Unit
Flinders University, Adelaide, Australia
Email: ladan.sahafi@flinders.edu.au

ABSTRACT

Background
Obesity is a risk factor for osteoarthritis and total hip/knee joint replacement and can also lead to poorer outcomes following surgical interventions. Self-management programs are a recommended approach for addressing clinical features of osteoarthritis and obesity.

Aims
This study investigates the relative efficacy of the Flinders chronic condition self-management program versus treatment as usual in obese patients with hip or knee osteoarthritis on a knee/hip joint replacement waiting list.

Methods
Obese (Body Mass Index or BMI≥30) osteoarthritis patients on a knee/hip joint replacement waiting list will be assessed for study eligibility. 95 consented patients will provide 80 per cent power to detect an effect size of 0.6 in the primary outcome measure of quality of life at 6 months and 10 months, at α=10 per cent level. A randomised sequence, stratified by gender and obesity class will be generated and administered by a computer-based system. Health-related quality of life outcomes will be collected using Short Form SF-36 and OAKHQOL at 6 and 10 months pre- and post-operatively. The main analysis will investigate differences in SF-36 scores between the intervention and treatment as usual groups on an intention-to-treat basis. Linear mixed effect models will be used to analyse outcome data.

Conclusion
This study is designed to provide robust and transparent findings including randomisation sequence generation, allocation concealment and implementation and will therefore provide much needed quality evidence in the field of self-management and osteoarthritis.[1] The Flinders Program has not been used in this type of patient cohort before and since it has been proven a successful self-management tool for other chronic conditions in Australian communities, the results of this study will add valuable knowledge to the chronic condition management.

Key Words
Obesity, osteoarthritis, chronic condition self-management, randomised controlled trial, quality of life

What this study adds:

1. What is known about this subject?
Obesity is a risk factor for osteoarthritis and hip/knee joint replacement. Self-management is a recommended approach for addressing both obesity and osteoarthritis.

2. What new information is offered in this study?
The Flinders chronic condition self-management support is tailored to target obese patients with osteoarthritis in order to improve health-related quality of life.

3. What are the implications for research, policy, or practice?
With the prevalence of obesity and osteoarthritis

increasing, finding an approach to address both is critical.

Background

Osteoarthritis is characterised by the inflammation of the synovial membrane of joints and the progressive breakdown of joint cartilage, resulting in pain and stiffness,[2] and can lead to significant disability and functional limitations (e.g. walking).[2] The increasing prevalence of osteoarthritis is well documented in epidemiological reports, for example, in Australia there was a rise from 7.5 per cent in 2008 in the osteoarthritis prevalence to 8.1 per cent in 2014.[3] As life expectancy increases, the prevalence of osteoarthritis is expected to increase.[4,5]

The most prevalent extrinsic risk factor for osteoarthritis is obesity which is also the most modifiable risk factor.[6] There is a positive association between obesity and both hip and knee osteoarthritis.[7,8] Although total knee or hip joint replacement (TKR/THR) is the most effective treatment for improving function and reducing pain in patients with advanced knee or hip osteoarthritis, poorer outcomes are experienced for obese patients.[9] The impact of obesity on functional outcome, pain and complications following TKR/THR have been well studied with obesity being reported as an indicator of higher rates of complications, and lower improvement in pain and functional outcomes, although the latter with some controversy.[10-16] Studies evaluating the impact of obesity on Health-Related Quality-of-Life (HRQoL) outcomes of TKR/THR are on the other hand, limited and lack methodological rigour.[17-20]

Chronic disease self-management programs have shown to have some benefits for both physical and psychological aspects of chronic conditions and associated risk factors.[21-23] Self-management has been used in the treatment for osteoarthritis,[6,23] and is also a recommended method of addressing obesity which may require changing habits, and therefore well-developed self-regulatory skills, consistency and timeliness.[24] A well-developed self-management support program may help obese osteoarthritis patients improve HRQoL by controlling the chronic condition, improving their lives and potentially assisting in their weight loss. A previous systematic review has suggested that self-management programs offer modest benefits for people with osteoarthritis; but these findings were tentative due to mostly low quality studies e.g. a lack of transparency in reporting randomisation methods or concealment of allocation. This highlights the need for more robust studies to be reported according to the Consort guidelines.[1] This proposed study will add to the evidence-base through rigorous reporting of all aspects of the study including randomisation procedures, and to the best of our knowledge it will be the first study to evaluate a self-management program in people with both osteoarthritis and obesity.

While different types of self-management programs have been used, they generally aim to increase active participation of the person with the condition in monitoring their health, making decisions about care, or both. Self-management support programs mostly come in either of two types: disease-specific patient education programs or lay-led programs. Disease-specific programs provide organised learning experiences designed to facilitate the adoption of health-promoting behaviours for one particular condition, and are usually delivered by health professionals. These programs have been criticised for the many people dealing with multiple morbidities. Lay-led group programs aim to improve participants' confidence in managing both their chronic conditions, in partnership with health professionals, and their lives.[22]

Flinders program was developed based on Stanford program. A major feature of the Flinders Program is that it addresses both patient behaviours and clinician behaviours that are necessary for sustained gain in health outcomes. The Program provides a generic set of tools and a structured process that enables health workers and patients to collaboratively assess self-management behaviours, identify problems, set goals, and develop individual care plans covering key self-care, medical, psycho-social and carer issues.[22]

The Flinders Chronic Condition Management Program, developed by Battersby et al. is an individualised generic self-management support program which has the flexibility to be combined with targeted disease-specific interventions.[22,25] The Flinders Program has been validated and successfully implemented for various target groups including patients with obstructive sleep apnoea, and Vietnam veterans with co-morbid alcohol misuse and psychiatric and medical conditions.[22,25-27] It has also been implemented in Aboriginal communities with complex chronic conditions such as diabetes, heart disease and respiratory illness.[28] The benefits experienced by a diverse cohort of sub-populations from the Flinders Program, reflect its generic properties for a broad range of disorders and risk factors. It may be that the Flinders Program can provide a mechanism for patients who suffer from osteoarthritis and co-occurring obesity to better manage their conditions and subsequently experience improvements in quality of life.

Therefore, the aim of this study is to evaluate the efficacy of the self-management support Flinders Program in improving Health-Related Quality of Life for obese hip or knee osteoarthritis patients on a total knee or hip joint replacement waiting list, in six months of intervention. A further aim is to determine whether self-management competency is associated with weight loss for this cohort of patients.

Method

Study design

Evaluating the impact of the Flinders Program on HRQoL in obese osteoarthritis patients is a two-group randomised, parallel design with patients on a total knee or hip joint replacement waiting list registered at the Repatriation General Hospital in Adelaide, South Australia. The study will recruit 94 patients over a 6-month enrolment period starting July 2015 and follow-ups at 6-month and 10-month. Eligible patients will be randomised to either a control group receiving usual care or an intervention group receiving the Flinders Program for six months. The study has received approval from the Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC), and was registered with the Australian New Zealand Clinical Trials Registry (ACTRN12615000674538).

Eligibility for participation

Patients will be invited to participate if they meet the following criteria: Have a BMI of 30 kg/m² or above; have been on the knee or hip joint replacement waiting list due to osteoarthritis and willingly provide signed informed consent form to participate in the study. Patients with the following criteria will be excluded from the study: have a BMI of under 30 kg/m², have an emotional or neurological condition that would pre-empt their ability or willingness to participate in the study including mental illness, intellectual disability, drug or alcohol abuse, as reported to the hospital's waiting list by the patient's GP; have had a surgery within the past three months; have dementia. Patients who have a pacemaker or Implantable Cardioverter Defibrillator (ICD) will be excluded from the body fat measurement test.

Participant recruitment

Participants will be drawn from osteoarthritis patients who are on the knee or hip joint replacement waiting list of Repatriation General Hospital. Eligible participants will initially be identified through patient information provided by the staff at the Repatriation General hospital, and sent an invitation letter to participate in the study along with the patient information sheet. The project officer will then make a follow-up phone call to individual patients to ascertain their willingness to participate in the study. For patients who agree to be in the study a visit time to obtain written consent and enrolment will then be arranged.

Sample size

The primary research question is: Does the Flinders Program plus treatment as usual improve HRQoL for obese osteoarthritis patients on a total knee or hip joint replacement waiting list compared to treatment as usual only? The Flinders Program is a safe intervention and little harm in the widespread application of such a program is expected. In fact, some benefits such as self-management competency might be gained, even if the Flinders Program does not directly reduce obesity or improve all aspects of HRQoL. Therefore, any penalties of a type I error will be nominal. In contrast, the consequences of a Type II error may have a more negative impact since a safe, inexpensive, and possibly effective intervention may be missed. In such exploratory studies, there is a strong rationale for using a less stringent statistical significance (i.e. α=0.10).[29] This design parameter is frequently used in exploratory or phase II studies including those involving biological and psychotherapeutic interventions.[30,31] Also, as the control group in this study will receive usual care, which only includes general information and no further attention, a clinically meaningful difference with moderate effect size is expected in favour of intervention group. Therefore, based on a type I error rate of 10 per cent, power of 80 per cent, two-tailed test, to detect an effect size of 0.6, 36 participants in each arm are required. Stata13 was used to calculate the sample size.[32] With an anticipated dropout rate of 30 per cent, we would need to recruit 47 participants in each group of the study, resulting in a total sample size of 94 participants.

Randomisation and allocation concealment

Following enrolment of participants, baseline assessments will be conducted. Then participants will be randomly assigned to one of two groups, either control or intervention with a 1:1 allocation ratio. Randomisation will be blocked to ensure approximately similar group sizes, using varying block sizes to protect concealment. To achieve balance in each arm on observed patient characteristics, randomisation will also be stratified on gender and BMI groups. BMI groups will be stratified as 30-34.9 (obese), 35-39.9 (severely obese), 40 and above (morbidly obese). A biostatistician will independently generate stratified blocked randomisation sequences using Stata 14.1 (StataCorp, College Station, TX, USA) statistical software and deliver to the clinical trial pharmacy at Repatriation General

Hospital. Once baseline measurements are taken for each participant, an independent staff member will assign the next random allocation by emailing the gender and BMI group of the participant to the clinical trial pharmacy, and receiving the allocation group.

Treatments

The control group will receive the usual care from physiotherapists, general practitioners and community services (e.g. RDNS – Royal District Nursing Service) after attending an information session at the hospital where a nurse from the hospital and an expert from Arthritis Australia provide guidance to manage their chronic condition.

Participants in the intervention group will receive the usual care as well as the Flinders Program which will be delivered by a nurse who is trained at FHBHRU (Flinders Human Behaviour and Health Research Unit) prior to the start of the study. The Flinders Program will be delivered in an individual format in one face-to-face session and fortnightly follow up phone calls for six months, on a day and time agreed between the nurse and the patient. The Flinders Program education leader will regularly supervise the delivery of the program. During the initial face-to-face session of the Flinders Program, the participant will fill out the self-rated Partners in Health Scale (PIH). The Partners in Health (PIH) scale is a short and precise tool comprising of 12 self-rated items to reflect the definition of chronic condition self-management.[22] The intervention administering nurse will then explore the same questions in the form of a Cue and Response Interview (C&R) rating from her perspective, shared with the patient. Problem and Goals assessment (P&G) tool is then used to determine patient-identified problems and formulated goals to address those problems. These will be used to produce a fully negotiated care plan including identified priorities issues, management aims, agreed interventions, responsibilities and review dates. The initial session takes approximately one hour. After the initial session, participants will be provided follow-ups 2-4 weekly for six months to monitor progress, provide feedback and motivation, and problem solving training.

Blinding

Baseline measurements will be obtained before randomisation and are therefore free of any assignment-related bias. Since participants are informed that the intervention is a self-management support program, they will therefore be aware of whether or not they are receiving such a program. Participant information sheets also inform participants of potential benefits of both control and intervention programs, and therefore equipoise nature of the study. Participants will be advised not to discuss their allocation with data collection staff. Clinicians delivering the Flinders Program will be un-blinded. Random assignments will be concealed from data collection staff and will be recorded in a separate database accessed from a separate computer. Data analysts will be blinded to treatment allocation by the use of non-informative labels for the treatment group variable.

Measures

Demographic data including age as a continuous variable, gender, living arrangements (alone, with partner, with children, other), work status (unemployed, retired, full-time job, part-time job), and education level (primary school, secondary school, Bachelor degree, postgraduate) will be collected. In addition to demographic data, the following measures will be collected. The measures are presented in Table 1.

Outcome Measures

Outcome measures will be administered at baseline assessment, pre-surgery (approximately 6-months post-baseline) and 10-month post-baseline visits. In order to detect changes in Health-Related Quality of Life during intervention and at follow-ups, HRQoL will be quantified as the primary outcome measure. In order to thoroughly assess HRQoL, the use of both generic and disease-specific instruments is recommended. The generic 36-item Short-Form Health Survey (SF-36) questionnaire will measure HRQoL in eight domains of physical functioning, role limitations due to physical problems, bodily pain, general health perception, vitality, social limitation owing to emotional problems, role limitations due to emotional problems and mental health. The disease-specific OAKHQOL (Osteoarthritis of Knee or Hip Quality of Life) measures HRQoL in five domains of physical activities, mental health, pain, social support, social functioning.[33] This instrument is a 43-item scale with common problems for osteoarthritis patients, where each item is rates on a 1-10 Likert scale, and has been validated in previous studies.[34,35] As pain and function are both very important for patients, these aspects of quality of life will be measured as part of both SF-36 and OAKHQOL.

One of the secondary outcomes is self-management competency which will be measured using Partners in Health (PIH) Scale of the Flinders Program. In conjunction with patient assessment and goal setting processes, it is an important part of Flinders Program, and is structurally valid instrument for measuring chronic condition self-

management in an Australian community.[36] The PIH is a 12-item questionnaire based on the seven principles of self-management.[37] Changes in self-management competency will be assessed by comparison of changes in the control group and the intervention group between baseline and follow up and between groups over time. This will examine whether the changes in self-management competency that take place can be attributed to the Flinders Program. PIH has been validated in previous studies.[37]

Obesity is another secondary outcome which has to be monitored. The scale of obesity is commonly measured using BMI, an index based on height and weight information. However, it is now known that BMI as an index of obesity has a number of limitations such as its inability to distinguish between fat mass and fat-free mass.[38] Nevertheless, BMI still provides a simple and straightforward method of measuring obesity. In order to balance the limitations of BMI, two simply achievable central obesity measurements, namely Waist Circumference (WC) and Waist-to-Height Ratio (WHtR) will be taken.[38] In order to have a more accurate body composition measurement to compensate for limitation of anthropometric measures of BMI, WC and WHtR in estimating body composition and obesity,[39] whole body fat percentage will also be measured using a MF-BIA device (IMP^{tm} SFB7 Bio Impedance Spectroscopy-ImpediMed, a validated measurement tool). The IMP^{tm} SFB7 is a single channel, tetra polar bioimpedance spectroscopy (BIS) that scans 256 frequencies between 4 kHz and 1000 kHz. The device utilises Cole modelling with Hanai mixture theory to determine total body water (TBW), extracellular fluid (ECF) and intracellular fluid (ICF) from impedance data. Fat-free mass (FFM) and fat mass (FM) are then calculated on the device. People with a pacemaker or Implantable Cardioverter Defibrillator (ICD) are not recommended to be tested using this device, and are therefore excluded from this test.

Questionnaires will be mailed out if participants do not attend their follow up appointments to ensure maximum return rate.

Process Evaluation

Intervention process will be evaluated using Cue & Response, and Problems & Goals scores which will be collected from intervention participants at baseline and 6 months follow-ups or pre-operation. These scores present the level of compliance as well as the effects of the intervention program on the specified problems and goals.

Study Management

Monitoring Adverse Events

It is not anticipated that this study will result in any adverse emotional, psychological or physical events. However, should any adverse events arise as a result of the study; the patient will be referred to the appropriate health professional for further care. In the event of any adverse events, these will be reported to the Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC) immediately.

Data Management

Data will be entered by a staff member. Data files will be held on a secure database and backed up daily.

Study Drop-outs

Participants will be advised that they can voluntarily withdraw from the study at any time. Where a participant withdraws from the study, the reason(s) will be enquired and will be documented in the study results.

Treatment Drop-outs

Non-compliance participants in the intervention group will not be considered drop-out to reflect the efficacy of the program in real world. The level of treatment adherence for each participant will contribute to data analyses in the following section.

Data Analyses

All statistical analyses will be conducted using Stata 14.1 (StataCorp, College Station, TX, USA) software. The primary analysis will be intent-to-treat (ITT) to identify any statistically significant differences in SF-36 scores over time for the treatment and follow-up period, between Flinders Program and the usual care groups. To account for participant attrition and lack of treatment adherence, an 'as treated' and 'per protocol' analysis will also be conducted. The 'as treated' approach will help establish associations between clusters of participant characteristics and treatment outcomes from an observational perspective. The 'per protocol' analysis will be used to evaluate treatment efficacies for participants who adhere to their assigned treatment protocol. Secondary measures will be analysed using the same approach as outlined above.

Linear mixed models will be used for repeated measures of primary and secondary continuous and categorical outcomes. Fixed effects in models will include treatment group, time points of baseline, 6 and 12 month follow-up and interaction between group and time. Random effects will be at the study participant level and represent an

upward or downward shift in the outcome measure from an overall regression line and the rate of change over time. Linear combinations of regression coefficients will be tested for treatment group effect at the completion of the intervention period and for maintenance effects, and estimates will be presented along with 95 per cent confidence intervals. Predicted estimates of treatment outcomes at each time point will be calculated using fitted models of the data in order to examine patterns of individual change within each group.

The reporting of this trial will comply with CONSORT (Consolidated Standards of Reporting Trials) guidelines for nonpharmacological treatments.[40]

Qualitative Component

After the intervention period, approximately 8 to 12 participants from the intervention group will be invited to be interviewed about their perceptions and experiences of the Flinders Program. Purposeful sampling will ensure reflecting a range of individual experiences including treatment adherers and non-adherers. Interviews will be transcribed and documented, and then analysed using thematic analysis.

Baseline Results

Participant recruitment and flow

The flow of participants through each stage of the study is shown in Figure 1. Participants were recruited from a total of 218 patients on the hip or knee joint replacement waiting list. The most common reason for study exclusion was residential distance from the hospital, making it difficult to attend visits.

Baseline characteristics

Baseline socio-demographics for n=95 participants are presented in Table 2. Minimum age of participants was 45 and maximum 84. There were 20 participants younger than age of 60, 10 of whom have full-time or part-time jobs.

Baseline characteristics for n=95 participants are presented in Table 3. When stratifying BMI groups, there were 33 (34.7 per cent) obese, 41 (43.2 per cent) severely obese and 21 (22.1 per cent) morbidly obese.

Discussion

The design of this trial is guided by ethical considerations, and the study was approved by the Southern Adelaide Health Service Ethics committee.

Self-management support is a recommended treatment for both osteoarthritis and obesity, and to our best knowledge, its impact on HRQoL of patients with both obesity and osteoarthritis has not been studied in a robust and transparent study before. This study will contribute key information to treatment of obese osteoarthritis patients before a knee or hip joint replacement surgery. The one-on-one nature of the Flinders Program will also provide valuable information about dealing with multiple chronic conditions as many of the studied cohort have multiple chronic conditions. The qualitative interviews will further explore the treatment effects from the participants' perspective and complement the quantitative outcomes in drawing an extensive view of the intervention in practice.

A key strength of this study is the broad inclusion criteria and the fact that a considerable number of participants have comorbidities such as other chronic conditions, e.g. diabetes, asthma, etc., which will increase the external validity of the findings of this study. Another strength of this study includes the robustness in design and transparency in reporting the details of the design, enrolment, randomisation and other details, so that the results of this study could be reliable.

We stratified our randomisation for gender and BMI groups. Other potential cofounders such as comorbidity could be considered in future studies. However, due to the relatively small sample size in our study, further stratification could potentially lead to treatment group imbalance. Future large scale studies should also investigate sub-populations including complex comorbid conditions (e.g. a patient with knee osteoarthritis, depression and tobacco dependence). In addition, a further limitation is that this study will be conducted at a public hospital with a higher likelihood of treating patients with low socio-economic status, which might affect the outcomes.

Conclusion

The rationale and protocol for a randomised controlled trial to investigate the impacts of the self-management support Flinders Program on Health-Related Quality of Life of obese osteoarthritis patients was described. To our knowledge, this is the first randomised controlled trial to evaluate self-management support for this cohort. The data collected in this trial will provide a high-quality basis for future application of self-management support in clinics.

References

1. Kroon FP, van der Burg LR, Buchbinder R, et al. Self-management education programmes for osteoarthritis. The Cochrane Library. 2014 Jan 1.
2. Sokolove J, Lepus CM. Role of inflammation in the pathogenesis of osteoarthritis: latest findings and interpretations. Therapeutic advances in musculoskeletal disease. 2013 Apr 1;5(2):77–94.
3. Arthritis Australia. Time to Move: Osteoarthritis - A national strategy to reduce a costly burden 2014.
4. Dowsey MM, Choong PF. Predictors of pain and function following total joint replacement. INTECH Open Access Publisher; 2013.
5. Fernandes L, Hagen KB, Bijlsma JW, et al. EULAR recommendations for the non-pharmacological core management of hip and knee osteoarthritis. Annals of the rheumatic diseases. 2013 Jul 1;72(7):1125–35.
6. Clouet J, Vinatier C, Merceron C, et al. From osteoarthritis treatments to future regenerative therapies for cartilage. Drug discovery today. 2009 Oct 31;14(19):913–25.
7. Bliddal H, Leeds AR, Stigsgaard L, et al. Weight loss as treatment for knee osteoarthritis symptoms in obese patients: 1-year results from a randomised controlled trial. Annals of the rheumatic diseases. 2011 Aug 5:annrheumdis142018.
8. Holliday KL, McWilliams DF, Maciewicz RA, et al. Lifetime body mass index, other anthropometric measures of obesity and risk of knee or hip osteoarthritis in the GOAL case-control study. Osteoarthritis and Cartilage. 2011 Jan 31;19(1):37–43.
9. Felson DT, Lawrence RC, Dieppe PA, et al. Osteoarthritis: new insights. Part 1: the disease and its risk factors. Annals of internal medicine. 2000 Oct 17;133(8):635-46.
10. Dowsey MM, Choong PF. The utility of outcome measures in total knee replacement surgery. International journal of rheumatology. 2013 Oct 31;2013.
11. Inacio MC, Kritz-Silverstein D, Paxton EW, et al. Do patients lose weight after joint arthroplasty surgery? A systematic review. Clinical Orthopaedics and Related Research®. 2013 Jan 1;471(1):291–8.
12. Huddleston JI, Wang Y, Uquillas C, et al. Age and obesity are risk factors for adverse events after total hip arthroplasty. Clinical Orthopaedics and Related Research®. 2012 Feb 1;470(2):490–6.
13. Kerkhoffs GM, Servien E, Dunn W, et al. The influence of obesity on the complication rate and outcome of total knee arthroplasty. J Bone Joint Surg Am. 2012 Oct 17;94(20):1839–44.
14. Michalka PK, Khan RJ, Scaddan MC, et al. The influence of obesity on early outcomes in primary hip arthroplasty. The Journal of arthroplasty. 2012 Mar 31;27(3):391–6.
15. Springer BD, Parvizi J, Austin M, et al. Obesity and Total Joint Arthroplasty A Literature Based Review. JOURNAL OF ARTHROPLASTY. 2013 May 1;28(5):714–21.
16. Waters TS. Should Hip and Knee Arthroplasty Be Restricted in the Obese? InControversies in Obesity 2014 (pp. 193-199). Springer London.
17. Baker P, Muthumayandi K, Gerrand C. Influence of body mass index (BMI) on functional improvements at 3 years following total knee replacement: a retrospective cohort study. PloS one. 2013 Mar 19;8(3):e59079.
18. Nunez M, Nunez E, Del Val JL, et al. Health-related quality of life in patients with osteoarthritis after total knee replacement: factors influencing outcomes at 36 months of follow-up. Osteoarthritis and Cartilage. 2007 Sep 30;15(9):1001–7.
19. Stevens M, Paans N, Wagenmakers R, et al. The influence of overweight/obesity on patient-perceived physical functioning and health-related quality of life after primary total hip arthroplasty. Obesity surgery. 2012 Apr 1;22(4):523–9.
20. Zhang ZJ, Zhao XY, Kang Y, et al. The influence of body mass index on life quality and clinical improvement after total hip arthroplasty. Journal of Orthopaedic Science. 2012 May 1;17(3):219–25.
21. McAlindon TE, Bannuru R, Sullivan MC, et al. OARSI guidelines for the non-surgical management of knee osteoarthritis. Osteoarthritis and cartilage. 2014 Mar 31;22(3):363–88.
22. Battersby MW, Harris M, Reed RL, et al. A randomised trial of the Flinders Program to improve patient selfmanagement competencies in a range of chronic conditions: study rationale and protocol. Australasian Medical Journal. 2010;1(3):198–204.
23. Nelson AE, Allen KD, Golightly YM, et al. A systematic review of recommendations and guidelines for the management of osteoarthritis: The Chronic Osteoarthritis Management Initiative of the US Bone and Joint Initiative. InSeminars in arthritis and rheumatism 2014 Jun 30 (Vol. 43, No. 6, pp. 701–712). WB Saunders.
24. Burke LE, Wang J, Sevick MA. Self-monitoring in weight loss: a systematic review of the literature. Journal of the American Dietetic Association. 2011 Jan 31;111(1):92–102.
25. Heatley EM, Harris M, Battersby M, et al. Obstructive sleep apnoea in adults: a common chronic condition in need of a comprehensive chronic condition

management approach. Sleep medicine reviews. 2013 Oct 31;17(5):349–55.
26. Battersby MW, Beattie J, Pols RG, et al. A randomised controlled trial of the Flinders Program™ of chronic condition management in Vietnam veterans with co-morbid alcohol misuse, and psychiatric and medical conditions. Australian and New Zealand Journal of Psychiatry. 2013 Jan 10:0004867412471977.
27. Lawn S, Schoo A. Supporting self-management of chronic health conditions: common approaches. Patient Education and Counseling. 2010 Aug 31;80(2):205–11.
28. Harvey PW, Petkov J, Kowanko I, et al. Chronic condition management and self-management in Aboriginal communities in South Australia: outcomes of a longitudinal study. Australian Health Review. 2013 Apr 30;37(2):246–50.
29. Piantadosi S. Clinical trials: a methodologic perspective. John Wiley & Sons; 2013 May 29.
30. Calcaterra V, Veggiotti P, Palestrini C, et al. Post-operative benefits of animal-assisted therapy in pediatric surgery: A randomised study. PloS One. 2015 Jun 3;10(6):e0125813.
31. Lieberman JA, Dunbar G, Segreti AC, et al. A randomized exploratory trial of an alpha-7 nicotinic receptor agonist (TC-5619) for cognitive enhancement in schizophrenia. Neuropsychopharmacology. 2013 May 1;38(6):968–75.
32. StataCorp. (2013). Stata: Release 13. Statistical Software. College Station, TX: StataCorp LP.
33. Rat AC, Coste J, Pouchot J, et al. OAKHQOL: a new instrument to measure quality of life in knee and hip osteoarthritis. Journal of Clinical Epidemiology. 2005 Jan 31;58(1):47–55.
34. Goetz C, Ecosse E, Rat AC, et al. Measurement properties of the osteoarthritis of knee and hip quality of life OAKHQOL questionnaire: an item response theory analysis. Rheumatology. 2011 Mar 1;50(3):500–5.
35. Rat AC, Guillemin F, Pouchot J. Mapping the osteoarthritis knee and hip quality of life (OAKHQOL) instrument to the international classification of functioning, disability and health and comparison to five health status instruments used in osteoarthritis. Rheumatology. 2008 Nov 1;47(11):1719–25.
36. Smith D, Harvey P, Lawn S, et al. Measuring chronic condition self-management in an Australian community: factor structure of the revised Partners in Health (PIH) scale. Quality of Life Research. 2016 Jan 1:1–1.
37. Petkov J, Harvey P, Battersby M. The internal consistency and construct validity of the partners in health scale: validation of a patient rated chronic condition self-management measure. Quality of Life Research. 2010 Sep 1;19(7):1079–85.
38. Sahafi L, Bramwell D, Harris M, Krishnan J, et al. A Practice-Focused Overview of Methods to Assess Obesity before Arthroplasty. Musculoskeletal Care. 2015 Dec 1;13(4):258–63.
39. Beechy L, Galpern J, Petrone A, et al. Assessment tools in obesity—Psychological measures, diet, activity, and body composition. Physiology & Behavior. 2012 Aug 20;107(1):154–71.
40. The CONSORT Flow Diagram 2010. Available from: http://www.consort-statement.org/consort-statement/flow-diagram.

ACKNOWLEDGEMENTS

The authors wish to thank Christine Doerr for delivering the Flinders Program to study participants.

PEER REVIEW

Not commissioned. Externally peer reviewed.

CONFLICTS OF INTEREST

The authors declare that they have no competing interests.

ETHICS COMMITTEE APPROVAL

This study has received approval from the Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC) Approval number 401.14.

Table 1: Measurements

Measurements	Intervention period		Maintenance period
	Baseline	**6 months**	**10 months**
Demographics	✓		
HRQOL			
SF-36	✓	✓	✓
OAKHQOL	✓	✓	✓
Self-Management			
PIH	✓	✓	✓
Obesity			
BMI	✓	✓	✓
WC	✓	✓	✓
WHtR	✓	✓	✓
%BF	✓	✓	✓
Intervention participants only:			
Cue & Response score	✓	✓	
Problems & Goals score	✓	✓	

Table 2: Baseline socio-demographics

Socio-demographic data	N=95
Age (years)	66.89 (8.64)
Female	58 (61)
Living arrangement	
Living alone	32 (30)
Living with partner / children	56 (60)
Other	6 (10)
Work status	
Retired / unemployed	78 (82)
Full-time job	7 (8)
Part-time job	9 (9)
Qualification	
Primary school	8 (8)
Secondary school	61 (64)
Undergraduate	10 (11)
Postgraduate	7 (7)
Other	9 (9)

Data are mean (SD), or n (%).

Table 3: Baseline clinical characteristics

Baseline characteristics	**N=95**
BMI	37.29 (4.75)
WC	118.74 (13.10)
WHtR	0.73 (0.07)
%BF	39.5 (8.81)
SF36	
Vitality	35.86 (20.18)
Physical function	27.00 (18.22)
Bodily pain	24.23 (14.75)
General health perception	56.02 (22.33)
Total physical score	31.57 (6.74)
Physical role	34.61 (22.42)
Emotional role	58.07 (31.19)
Social role	49.47 (32.36)
Mental health	65.07 (21.31)
Total mental score	45.71 (12.54)
OAKHQOL	
Physical Activity	36.63 (17.27)
Mental health	55.16 (25.54)
Pain	27.11 (21.03)
Social support	68.00 (22.51)
Social activities	59.28 (26.11)
Professional activities	49.67 (34.99)
Spouse relation	50.18 (35.73)
Sexual activities	46.00 (40.53)
Self-management (PIH)	77.97 (12.23)

Data are mean (SD), or n (%).

Figure 1: Participant flow