Trial Review

Trial registered on ANZCTR

Registration number	ACTRN12617000766314
Ethics application status	Approved
Date submitted	17/05/2017
Date registered	24/05/2017
Date last updated	15/05/2018
Type of registration	Prospectively registered

Titles & IDs

Public title	FitSkills: a community-university partnership to increase exercise participation among youth with disability
Scientific title	FitSkills: a community-university partnership to increase exercise participation among youth with disability
Secondary ID [1]	None
Universal Trial Number (UTN)	
Trial acronym	
Linked study record	

Health condition

Health condition(s) or problem(s) studied:

Disability

Condition category	Condition code
Physical Medicine / Rehabilitation	Physiotherapy
Musculoskeletal	Other muscular and skeletal disorders
Neurological	Other neurological disorders

Intervention/exposure

Study type	Interventional
Description of intervention(s) / exposure	The intervention is an exercise program called FitSkills. The program matches a young person with disability with a mentor from their community and the pair exercise together at their local public gym (one-to-one), for an hour, twice a week for 12 weeks (24 sessions in total). The program comprises individually tailored exercise and plans for on-going participation in exercise. The exercise content comprises weight and aerobic training, individually tailored to the young person with disability. The exercise program (including the intensity) will be prescribed by members of the research team according to international guidelines from the American College of Sports Medicine (ACSM). The exercise program will be planned with the young person with disability and their family through a telephone interview and incorporating details from their baseline assessment to help determine what their training goals are, their preferences for type of exercise and their impairment(s).

The intervention also includes a transition phase in the final weeks to plan ongoing participation in exercise after FitSkills. This transition phase will comprise a face-to-face session with a member of the research team to help the participant plan their on-going participation in exercise and/or physical activity (e.g. what activity, where it will be done, who it will be done with, cost, equipment required) and a booklet with information about benefits of continuing to exercise, how they can participate in exercise and where they can participate in exercise.

The mentor exercises with the young person with disability. The mentors will be students enrolled in Allied Health courses (any discipline, any year level) at two universities in Melbourne, Australia (La Trobe University and Australian Catholic University). Mentors are volunteers who are selected based on residential location and will hold a current police and working with children check. Mentors are matched with a young person with disability from the same locality. All mentors complete a 3-hour face-to-face group training session on program content and motivational strategies conducted at either the university campus or at the facilities of one of our partner organisations. The training will be delivered by a member of the research team. Mentors are provided with written materials that include information about disability, an outline of the exercise program and advice for how the program should be delivered.

As mentors may not have pre-existing knowledge of exercise training or disability, they will maintain fortnightly contact with a member of the research team to address issues that arise, and to ensure that the intervention is being carried our as per protocol (i.e. the team member will check that the program continues to be delivered according to the ACSM guidelines). To monitor intervention fidelity, participants and mentors will document their programs in an exercise logbook, including exercise type and dose, adverse events or missed sessions. The exercise logbooks will be collected at the end of the intervention and data about the program analysed by members of the research team (e.g. number of sessions attended or intensity progression for exercises performed). Analysis of the exercise logbook data will help identify any issues with intervention fidelity and this information will be used to maintain or improve fidelity at subsequent sites during roll-out of the program.

Intervention code [1] Rehabilitation

Intervention code [2] Lifestyle

Comparator / control treatment The study design is a stepped wedge cohort design with 8 sites and 4 cluster groups. This design sequentially introduces the intervention to 8 gyms (sites) in random order. After an initial 3-month baseline period when no sites are exposed (control phase), at 3-month intervals sites are randomised to cross from control to intervention phase until all sites have implemented FitSkills. Each gym site represents a cluster unit. The trial design will comprise four cluster groups each containing two randomly allocated cluster units. One cluster group (2 sites) will commence the intervention every 3 months. A member of the research team who is not involved in recruitment, assessment or delivery of the intervention, will randomise the order of the 8 sites using web-based software.

Control group Active

Outcomes

Primary outcome [1] Feasibility: will be measured: (1) using data from our partner organisations to map numbers of their constituents living close to FitSkills sites and comparing to the number of enrolments; (2) comparing numbers of enquiries with enrolments in FitSkills; (3) documenting wait-lists and mentor expressions of interest; (4) using data from exercise logbooks documenting attendance and involvement during FitSkills, intervention fidelity (including exercise intensity), and adverse events; (5) gaining perspectives of youth with disability, their families and mentors, and gym management and staff on FitSkills from semi-structured interviews; Data on the experience of youth with disability of the gym context will also be measured by the Self-reported Experiences of Activity Settings and Measure of Environmental Qualities of Activity Settings questionnaires; and (6) reviewing each site's disability policy and procedures using National Information Communication Awareness Network (NICAN) guidelines.

Timepoint [1] (1) Mapping of the numbers of members from partner organisations living close to sites will occur prior to recruitment. These numbers will be and compared to the number of enrolments immediately before implementation of the intervention at each site.
(2) The number of enquiries will be compared with the numbers of enrolments in FitSkills immediately before implementation of the intervention at each site
(3) numbers of our wait-lists and mentor expressions of interest will be documented at 3-month intervals throughout the 2 year data collection period
(4) data from exercise logbooks documenting attendance, adherence (intervention fidelity) during FitSkills, and adverse events will be analysed at the end of each program.
(5) the perspectives of youth with disability, their families and mentors, and gym management and staff on FitSkills from semi-structured interviews will be collected immediately after the intervention. Questionnaires about the experience of youth with disability of the gym context will be measured immediately after the program also.
(6) a review of each site's disability policy and procedures using National Information Communication Awareness Network (NICAN) guidelines will be performed prior to the implementation of FitSkills

Primary outcome [2] Participation has two essential components: attendance (being there) and involvement (experience of participation). Attendance (type, frequency) will be measured using Adolescent Physical Activity Recall, Adolescent Sedentary Activity and 16 physical activity items from Children's Assessment of Participation and Enjoyment questionnaires.

Timepoint [2] Measured every 3 months from participant enrolment in the trial until completion of the trial (24-months).

Primary outcome [3] Involvement (experience of participation) will be measured using youth self-report of the community

	section of the Participation and Environment Measure-Children and Youth.
Timepoint [3]	Measured every 3 months from participant enrolment in the trial until completion of the trial (24-months).
Secondary outcome [1]	Health-related quality of life of the youth with disability will be measured using the 9-item Child Health Utility instrument. This is an additional primary outcome.
Timepoint [1]	Measured every 3 months from participant enrolment in the trial until completion of the trial (24-months).
Secondary outcome [2]	Economic analysis (composite outcome), taking a societal perspective, will be completed. Data to inform the economic analysis will be collected from participants and their families on socioeconomic status (employment, income, carer requirement, leisure), attendance (time, travel, out-of-pocket expenses) and health service use if injured (hospital attendance, admission, consultations, investigations). Data will be collected from mentors to determine their participation (time, travel, out-of-pocket expenses). Mentor time will be costed at university rates. Annual cost of capital (equipment, space) at the sites will be costed according to the opportunity cost method. Reasonable rental equivalent will be used to cost space. Incremental cost effectiveness ratios (ICERs) expressed as cost per quality adjusted life years saved will be calculated comparing costs and health related quality of life outcomes between FitSkills and no intervention based on difference in costs and the health related quality of life utility index between the pre- and post-intervention periods.
Timepoint [2]	Economic data will be collected from all youth with disability, their families and mentors before the intervention and for at least 6 months after the intervention.
Secondary outcome [3]	Perception of wellbeing will be measured using the 20-item Life Satisfaction Scale.
Timepoint [3]	Measured every 3 months from participant enrolment in the trial until completion of the trial (24-months).
Secondary outcome [4]	Physical activity will be measured as minutes spent doing moderate intensity activity with an activity monitor (Actigraph) worn for 8 consecutive days (one day familiarisation).
Timepoint [4]	Measured every 3 months from participant enrolment in the trial until completion of the trial (24-months).
Secondary outcome [5]	Attitudes to exercise will be measured using the 9-item Exercise Outcomes Scale which assesses self-rated perceived benefits of exercise.
Timepoint [5]	Measured every 3 months from participant enrolment in the trial until completion of the trial (24-months).
Secondary outcome [6]	Barriers to exercise will be assessed using the 18-item Exercise Barriers Scale which measures perceived motivational, knowledge, accessibility, cognitive and social barriers to exercise for people with disability.
Timepoint [6]	Measured every 3 months from participant enrolment in the trial until completion of the trial (24-months).
Secondary outcome [7]	Exercise self-efficacy will be measured using the 5-item Self-Efficacy Measure which reports exercise performance self-efficacy pertaining to confidence in performing exercise.
Timepoint [7]	Measured every 3 months from participant enrolment in the trial until completion of the trial (24-months).
Secondary outcome [8]	Walking capacity will be measured using the six-minute walk test using a modified technique that allows continuous encouragement.
Timepoint [8]	Measured every 3 months from participant enrolment in the trial until completion of the trial (24-months).
Secondary outcome [9]	Attitudes to disability of student mentors will be measured using the 5-item Discomfort scale which indicates respondent's level of discomfort when interacting with people with disability.
Timepoint [9]	Measured every 3 months from participant enrolment in the trial until completion of the trial (24-months).
Secondary outcome [10]	Attitudes to disability of staff working at the 8 gym sites will be measured using the 5-item Discomfort scale which indicates respondent's level of discomfort when interacting with people with disability.
Timepoint [10]	Measured every 3 months from participant enrolment in the trial until completion of the trial (24-months).
Secondary outcome [11]	Attitudes to disability of gym patrons at the 8 sites will be measured using the 5-item Discomfort scale which indicates respondent's level of discomfort when interacting with people with disability.
Timepoint [11]	Measured every 3 months from participant enrolment in the trial until completion of the trial (24-months).

Eligibility

Key inclusion criteria	Youth with disability (including physical, intellectual, sensory disabilities) will be eligible for inclusion in the trial if: (1) they are 13-30 years, (2) can follow simple verbal instructions in English (as indicated by the Index of Social Competence) and (3) are medically fit to take part in a high intensity exercise program as determined by their responses to the Adult Pre-exercise Screening tool. If their responses to this questionnaire indicate a potential problem then they will be asked to get a medical clearance certificate to participate from their medical practitioner.
Minimum age	13 Years
Maximum age	30 Years
Gender	Both males and females
Can healthy volunteers participate?	Yes
Key exclusion criteria	Participants will be excluded if they: (1) participated in a high-intensity exercise program within 3 months prior to the trial; (2) have an acute or concurrent medical condition rendering them unfit to take part (e.g. severe cardiac conditions, severe osteoarthritis, uncontrolled epilepsy); or (3) have a significant behavioural problem that would impact on participation (e.g. resistive behaviour or severe depression or severe anxiety).

Study design

Purpose of the study	Treatment
Allocation to intervention	Randomised controlled trial
Procedure for enrolling a subject and allocating the treatment (allocation concealment procedures)	
Methods used to generate the sequence in which subjects will be randomised (sequence generation)	
Masking / blinding	
Who is / are masked / blinded?	
Intervention assignment	
Other design features	Embedded in an implementation science framework, our stepped wedge cluster randomised trial, using a cohort design, will compare the effect of FitSkills with a control phase. This design sequentially introduces FitSkills to gymnasia (sites) in random order. After an initial period when no sites are exposed (control phase), at regular intervals sites are randomised to cross from control to intervention phase until all sites have implemented FitSkills
Phase	
Type of endpoint(s)	
Statistical methods / analysis	

Recruitment

Recruitment status Recruiting

Date of first participant enrolment

Anticipated 2/10/2017 **Actual** 23/01/2018

Date of last participant enrolment

Anticipated **Actual**

Date of last data collection

Anticipated **Actual**

Sample size

Target 160 **Accrual to date** 100 **Final**

Recruitment in Australia

Recruitment state(s) VIC

Funding & Sponsors

Funding source category [1]	Government body
Name [1]	National Health and Medical Research Council
Address [1]	GPO Box 1421 Canberra ACT 2601
Country [1]	Australia
Funding source category [2]	Government body
Name [2]	Victorian Department of Health and Human Services
Address [2]	50 Lonsdale Street Melbourne, Victoria 3000
Country [2]	Australia
Funding source category [3]	Charities/Societies/Foundations
Name [3]	Disability Sport and Recreation
Address [3]	341 George St, Fitzroy,

	VIC 3065
Country [3]	Australia
Funding source category [4]	Charities/Societies/Foundations
Name [4]	YMCA VIctoria
Address [4]	40 Brougham St., Eltham, VIC 3095
Country [4]	Australia
Funding source category [5]	Charities/Societies/Foundations
Name [5]	Cerebral Palsy Support Network
Address [5]	525 High St., Preston, VIC 3072
Country [5]	Australia
Funding source category [6]	Charities/Societies/Foundations
Name [6]	Down Syndrome Victoria
Address [6]	18/71 Victoria Crescent, Abbotsford, Victoria 3067
Country [6]	Australia
Funding source category [7]	Charities/Societies/Foundations
Name [7]	Joanne Tubb Foundation
Address [7]	Suite 3, 21 Vale St., North Melbourne, VIC 3051
Country [7]	Australia
Funding source category [8]	Government body
Name [8]	Boroondara City Council
Address [8]	8 Inglesby Rd., Camberwell, VIC 3124
Country [8]	Australia
Primary sponsor type	University
Name	La Trobe University
Address	Kingsbury Drive, Bundoora, VIC 3086
Country	Australia
Secondary sponsor category [1]	None
Name [1]	
Address [1]	
Country [1]	

Ethics approval

Ethics application status	Approved
Ethics committee name [1]	La Trobe University Human Ethics Committee
Ethics committee address [1]	
Ethics committee country [1]	Australia
Date submitted for ethics approval [1]	
Approval date [1]	14/03/2017
Ethics approval number [1]	HEC 17-012
Ethics committee name [2]	Australian Catholic University
Ethics committee address [2]	115 Victoria Parade, Fitzroy VIC 3065
Ethics committee country [2]	Australia

Date submitted for ethics approval [2]	
Approval date [2]	27/03/2017
Ethics approval number [2]	2017-63R
Ethics committee name [3]	Deakin University
Ethics committee address [3]	221 Burwood Highway Burwood Victoria 3125
Ethics committee country [3]	Australia
Date submitted for ethics approval [3]	
Approval date [3]	10/08/2017
Ethics approval number [3]	2017-206

Summary

Brief summary	FitSkills is an exercise program that matches a young person with disability with a mentor and the pair exercise together at their local gym, for an hour, twice a week for 12 weeks. The program comprises individually tailored exercise and plans for on-going participation in exercise. Together with 7 partner organisations, we will complete a research translation project through a stepped wedge cluster randomised trial using a cohort design, with embedded health economics evaluation. The trial design sequentially introduces FitSkills to 8 gyms (sites) in random order. After a control period, at regular intervals sites are randomised to cross from control to intervention phase until all sites have implemented FitSkills. We will recruit 160 youth with disability (any type) aged 13-30 years through our partner organisations. Data collection at 8 time points will continue throughout the trial at 3-month intervals (i.e. an assessment is conducted every 3 months for 24 months). We will collect data on: participant demographics and socioeconomics; participation; health-related quality of life; physical activity; attitudes to exercise; walking capacity; program feasibility; and attitudes to disability for mentors, gym staff and gym patrons at the participating sites.
Trial website	
Trial related presentations / publications	
Public notes	

Contacts

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No data has been provided for results reporting

Summary results

Not applicable

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