PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	How effective is community physical activity promotion in areas of deprivation for inactive adults with Cardiovascular Disease risk and/or mental health concerns? Study protocol for a pragmatic observational evaluation of the 'Active Herts' physical activity programme
AUTHORS	Howlett, Neil; Jones, Andrew; Bain, Lucy; Chater, Angel

VERSION 1 – REVIEW

REVIEWER	Fawn Yeh University of Oklahoma Health Sciences Center USA
REVIEW RETURNED	18-Jun-2017

GENERAL COMMENTS	The aims of this study are to test the effectiveness, acceptability, and sustainability of physical activity programs. It is an interesting study; however, the study methods were not clearly stated which makes the study questionable. 1). Methods: Eligibility of program users. In the paragraph, the inclusion criteria for participants are adults who have one or more CVD risk factors (diabetes, hypertension, high cholesterol, obesity); those who are inactive with a mild or moderate mental health will also be included. In my opinion, mixing participants with mental health problem with participants with chronic conditions in the same program is not appropriate, detailed description about how to conduct study for these two group need to be stated. In addition, methods of measuring CVD risk factors (diabetes, hypertension, high cholesterol, obesity) and mental health conditions were not clearly defined and stated. 2). Methods: Program and evaluation materials and procedure. Based on Figure 1, the program will be delivered through “standard delivery” and “enhanced delivery”; the main difference between these two methods was that in the “enhanced delivery” group, an exercise buddy will be added. To my knowledge, most participants with mental conditions will not be able to handle program without exercise buddy, the effects of the study for this group of participants in the “standard delivery” arm will hardly be seen. Whether the “enhance delivery” is designed for participants with mental health problem is not clearly stated in the manuscript.

	3). Methods: Outcome measures - Primary outcomes will be assessed by Physical Activity Questionnaire, Secondary outcomes (mental well-being and perceptions of health) and COM-B measures will also be measure by questions. I would suggest including objective measures, such as using pedometer for physical activity measurement and measuring fasting glucose, blood pressure, cholesterol and height/weight (to calculate body mass index) for CVD risk factors' measurements. 4). Methods: The sustainability of the program. The authors need to describe the strategy of sustaining the program after 12 months of the study. In my opinion, keeping physically active requires lifelong efforts; 12 months trial would not be enough; community supports to make this program sustainable are needed.

REVIEWER	Hamid Najafipour Professor, Physiology Research Center, Kerman University of Medical Sciences, Kerman, Iran
REVIEW RETURNED	29-Jul-2017

GENERAL COMMENTS	This proposal is aiming to test the effectiveness of a community physical activity programme for inactive adults with one or more risk factors for CVD. The evaluation will follow a mixed-methods longitudinal design including assessing the outcomes of pragmatic delivery of a 12 weeks of exercise classes referred to them (standard delivery) in one group against a 12 weeks of free tailored exercise classes (enhanced delivery), with an exercise 'buddies' in the second group. An outcome evaluation of changes in physical activity as the primary outcome, and sporting participation, sitting, wellbeing, psychological capability, and reflective motivation as secondary outcomes will be assessed in the two groups. Economic evaluation will also examine the programme costs against the benefits gained in terms of reduced risk of morbidity. Overall the protocol is interesting, well described and well organized methodologically. However I have the following commeVnts to the present protocol: As the final goal of the study is reducing risk of CVD diseases in the target community, it would be much better to evaluate (as secondary outcomes) the prevalence and level of control of at least four main CAD risk factors, hypertension, diabetes, dyslipidaemia and overweight/obesity, which all are related to and affected by the level of physical activity. As the data are available and recorded regularly in the health files of the participants in UK, I think adding this part will not add much extra expenses to the protocol. These would be practical and extra indices for assessing the effectiveness of protocol to reduce the risk of morbidity. The risk factors may be assessed at two time intervals, at the baseline and at the end of study (even one year later). As an example the results of a population based CAD risk factor study (KERCADRS) has recently been published showing the prevalence of different CAD risks in an urban population along with assessing the effectiveness of national health programms in prevention and treatment of them. Diabetes: Journal of Diabetes, 2015 Sep; 7(5):613-21. Hypertension: International Journal of Public Health, 2014, 59 (6): 999-1009.

	Overweight and obesity: ARYA Atherosclerosis 2016; 12(1): 18-27. Dyslipidamia: Journal of Diabetes & Metabolic disorders, 2016, 15:49 DOI 10.1186/s40200-016-0268-0 Some minor changes in the protocol include: 1- Page 3 line 3: “this study was been approved” to “this study will be approved”. 2- Page 5 line 14: “Physical activity is responsible” to “Low physical activity is responsible”. 3- Figure 1 line 36: “3 month assessment” to “month 3 assessment” or “3-month assessment”. Also the same for lines 43 and 51 “6 month” and “12 month” assessments. 4- Page 13 line 48: “from ranging from” to “from ranging of”.

VERSION 1 – AUTHOR RESPONSE

Reviewer 1 comments:

1). Methods: Eligibility of program users. In the paragraph, the inclusion criteria for participants are adults who have one or more CVD risk factors (diabetes, hypertension, high cholesterol, obesity); those who are inactive with a mild or moderate mental health will also be included. In my opinion, mixing participants with mental health problem with participants with chronic conditions in the same program is not appropriate, detailed description about how to conduct study for these two group need to be stated. In addition, methods of measuring CVD risk factors (diabetes, hypertension, high cholesterol, obesity) and mental health conditions were not clearly defined and stated.

Response: Thank you for the suggestions. The key inclusion criteria is that programme users are inactive. Programme users may also have an additional CVD risk factor. We have made minor changes in the wording in this passage to emphasise this more clearly. CVD risk factors and mental health conditions are not measured by the project team. Eligibility is indicated by the GP using a referral form, with boxes to tick signifying that the programme user is inactive, alongside any other CVD risk factor and/or mental health issue. Self-referred programme users answer an eligibility question about their inactivity only. We acknowledge that requirements for individual participants may be different but there is enough scope in this programme to tailor delivery to the individual through the consultations and provision of appropriate forms of physical activity. It may well be that activity provision in the two areas receiving standard delivery offer sessions appropriate for people with mental health issues. Also, people who have CVD risk factors such as obesity and diabetes will often present with mild to moderate mental health issues as well, so looking into the effectiveness of this programme for people with co-morbidities would be an important contribution. The four areas chosen had much higher than normal prevalence of CVD risk factors and mental health problems.

2). Methods: Program and evaluation materials and procedure. Based on Figure 1, the program will be delivered through “standard delivery” and “enhanced delivery”; the main difference between these two methods was that in the “enhanced delivery” group, an exercise buddy will be added. To my knowledge, most participants with mental conditions will not be able to handle program without exercise buddy, the effects of the study for this group of participants in the “standard delivery” arm will hardly be seen. Whether the “enhance delivery” is designed for participants with mental health problem is not clearly stated in the manuscript.

Response: In addition to the optional exercise buddy, programme users in the enhanced delivery areas will also get 12 weeks of free tailored exercise classes facilitated by the Get Active Specialists instead of 12 weeks of access to existing activity sessions in the local area. To our knowledge there is no research which explicitly states that people with mild to moderate mental health issues cannot handle exercise without a buddy. As stated in the previous point this programme allows flexibility in the activity consultation, advice, and activity sessions provided to each individual and is therefore able to cater to a wide range of programme users. Programme users will not be referred to this programme unless the health professional referrer believes them capable of engaging in it. Therefore, the standard and enhanced delivery are not explicitly designed for people with mental health problems.

3). Methods: Outcome measures - Primary outcomes will be assessed by Physical Activity Questionnaire, Secondary outcomes (mental well-being and perceptions of health) and COM-B measures will also be measure by questions. I would suggest including objective measures, such as using pedometer for physical activity measurement and measuring fasting glucose, blood pressure, cholesterol and height/weight (to calculate body mass index) for CVD risk factors' measurements.

Response: Although it would be beneficial to collect the outcomes listed, this is simply not feasible from a financial or resource perspective. This programme will deliver to in excess of 1500 programme users and represents 'real-world' research far removed from an RCT where researchers deliver the intervention and administer the outcomes measures. Also, as previously stated this is an ongoing project that has already undergone peer-review at the grant application stage and at ethical approval and therefore the design cannot be changed at this stage, even if it was feasible.

4). Methods: The sustainability of the program. The authors need to describe the strategy of sustaining the program after 12 months of the study. In my opinion, keeping physically active requires lifelong efforts; 12 months trial would not be enough; community supports to make this program sustainable are needed.

Response: The funding has been given for three years and the follow-up period has been agreed with the funder. Providing a 12 month programme already gives some degree of sustainability. Although, we agree that a healthy lifestyle requires lifelong effort we know of no programme that provides this level of monitoring for participants and so this is not realistic. Efforts are already underway to try to provide continuation funding so that the Get Active Specialists can continue in their roles beyond the end of the project. This does not however comprise part of the current project delivery and it is therefore not appropriate to include in this protocol.

Reviewer 2 comments:

Comment: As the final goal of the study is reducing risk of CVD diseases in the target community, it would be much better to evaluate (as secondary outcomes) the prevalence and level of control of at least four main CAD risk factors, hypertension, diabetes, dyslipidaemia and overweight/obesity, which all are related to and affected by the level of physical activity. As the data are available and recorded regularly in the health files of the participants in UK, I think adding this part will not add much extra expenses to the protocol. These would be practical and extra indices for assessing the effectiveness of protocol to reduce the risk of morbidity. The risk factors may be assessed at two time intervals, at the baseline and at the end of study (even one year later). As an example the results of a population based CAD risk factor study (KERCADRS) has recently been published showing the prevalence of different CAD risks in an urban population along with assessing the effectiveness of national health programms in prevention and treatment of them.

Response: We agree these outcomes will be important and although measuring them in this initial programme evaluation is not possible, the intention is to try to use surveillance data as one means of monitoring population impact of the programme in the future.

Page 3 line 3: “this study was been approved” to “this study will be approved”.

Response: As this protocol reports an ongoing study that has already been approved then this wording is correct

Page 5 line 14: “Physical activity is responsible” to “Low physical activity is responsible”.

Response: This sentence actually states that ‘physical inactivity is responsible’, which is another way of saying low physical activity so this has been left in.

Figure 1 line 36: “3 month assessment” to “month 3 assessment” or “3-month assessment”. Also the same for lines 43 and 51 “6 month” and “12 month” assessments.

Response: These have now all been changed to 3-month, 6-month, and 12-month assessment

Page 13 line 48: “from ranging from” to “from ranging of”.

Response: = This has now been changed

VERSION 2 – REVIEW

REVIEWER	Dr Hamid Najafipour Physiology Research Center, Kerman, Iran
REVIEW RETURNED	22-Sep-2017

GENERAL COMMENTS	Reviewer comment The Authors have changed the title, one of goals and have done some minor typographic corrections in the revised manuscript. However as they have mentioned: -It is not possible to change the design of the project because the protocol reports an ongoing fully-funded and peer-reviewed project and therefore the suggested revisions to the methodology could not be accommodated. -The inclusion criteria, follow-up and outcomes have all been agreed with the funders. -The follow-up period has been agreed with the funder. - Suggested outcomes will be important but measuring them in this initial program evaluation is not possible. -We have changed all of the minor points and hope that this article is now ready for publication in BMJ Open. -We feel that your readership will find the study interesting and noteworthy. I hope you now judge this manuscript to be ready for publication in BMJ Open. Therefore they are not able to respond to any of the comments raised by the reviewers, yet they feel the Manuscript is already suitable for publication in BMJ Open!