Author's response to reviews

Title: Behaviour change to promote health and well-being in later life: the AgeWell study

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Author's response to reviews: see over
Reviewer's report
Title: Behaviour change to promote health and well-being in later life: the AgeWell study
Version: 1 Date: 8 May 2012
Reviewer: Marissa Lassere

Reviewer's report:
It is good to see that health promotion interventions being evaluated in RCTs. It is quite an ambitious project and one that appears to be quite resource intensive. The protocol is written well, in general clear, and well referenced.
1. Will the study design adequately test the hypothesis? Yes
2. Are sufficient details provided to allow replication of the work or comparison with related analyses: if not, what is missing? Uncertain - see below comments and questions below
3. Is the planned statistical analysis appropriate? Yes
4. Is the writing acceptable? Yes

Comment: Difficulties are the horizon (1, 2, and even 5 years) and what outcomes are being evaluated. Here they are based on questionnaires/instruments rather than important clinical outcomes such as reduction in hospitalizations, decrease serious out of hospital events, health promoting activities, actual social support etc.

Question/s: Have the authors considered what clinically important interventions they would consider in the main trial and should these not be implemented in this feasibility study?

The study assesses the efficacy of a goal-setting intervention in stimulating sustainable behaviour change for a range of generally healthy older people. It is not a clinical study or a clinical intervention. The main trial is expected to focus on similar domains. The study protocol outlines a number of cognitive, social, and health/physical outcomes measured by questionnaire and also both neuropsychological and physical tests. This includes assessment of participation in activities that are likely to promote health, and collection of information regarding use of health and social care services at baseline and follow-up. Our main focus at this stage is on whether it is possible to achieve sustainable behaviour change with new activity patterns incorporated into participants’ lifestyles, rather than on clinical outcomes. The study is funded as a development study and does not provide scope for longer-term follow-up.

Comment: My experience with undertaking research in the older population is their difficulty being able to complete many of the instruments that have been developed to evaluate emotional and mental well-being, physical well being, perceptions of social support, self-efficacy, learning and cognitive function and so forth. There is an issue of questionnaire burden although often this can be overcome if considered in advance. I counted approximately 15 instruments and interviews that the participants will need to complete. In addition to these the participants undergo an assessment of physical fitness, health and diet. I understand that this feasibility study will determine which instruments are carried over into the main RCT.
**Question/s How many pages of instruments are required?**
We are an experienced research team with a wealth of practice in working with older people and with people with dementia, and as such sensitive to testing issues and burden in working with older people. Measures and assessments have been selected accordingly. All measures are completed in a face-to-face session with a researcher. We did provide this information on page 16 but have amended the text to make it clearer. We have also added details of the length of the interviews. The assessment is divided into two parts. Each participant meets with a researcher for a 1.5 hour session in which most of the questionnaires are completed, and a 1 hour health and physical assessment is conducted on a separate occasion. To date, participants have found this acceptable. The intervention involves a further interview, lasting up to 1.5 hours. We have added a note about the length of this interview on page 7.

**Will the population that agreed to take part and who managed to get through this initial questionnaire evaluation be a biased subgroup - older but cognitively and motivationally inclined, and perhaps not as generalisable to others?**
This issue was taken into account in designing the study and is the reason why the study is being conducted in partnership with Age Cymru Gwynedd a Mon. This third sector organisation provides services and resources for older people and has a strong track-record of reaching hard-to-access and more socially disadvantaged groups. The AgeWell Centre aims to attract members of the community who are hard to reach as well as those who are active. From our initial testing sessions we have found that people with varying cognitive abilities and varying levels of physical health and fitness have agreed to participate. Clearly in any study there is always the possibility of self-selection and this has to be taken into account in interpreting findings. For this reason, we will examine and report the demographic profile of our participant group. A comment has been added in the discussion on page 19.

**Are there any exclusion criteria? If not will it be a consecutive or convenient sample and if the latter how are the researchers making their decision? That is, on what criteria will subjects be approached for participation?**
No exclusions were specified in the protocol, as stated on page 5. All individuals aged over 50 years, resident in the local community, who attend the AgeWell Centre are invited to participate. That is to say, we will work with any individual who attends the Centre, provided that individual wishes to participate. This information was provided on page 5. Centre staff log all attendances and this information is available to the researchers. Contact with potential participants is made in the course of their participation in the activities provided at the centre.

**I would like to see information collected regarding how many subjects were approached to take part and if they refused the reasons for refusal. Is this possible?**
Certainly this information is being collected and will be reported. We keep records of how many people are approached and either agree to participate or decline to take part. As centre attendees are free to decline to participate without giving any specific reason, we may not always know why they decline, but we record this information where it is provided. We have added this point on page 6. Further comment has also been made in the discussion on page 19.

**Are patients consented? If so are the questionnaires provided after consent? The design also should evaluate how many patients dropped out after attempting to complete the initial evaluation questionnaires? Also, the completeness of the**
questionnaires and whether assistance was needed for their completion?
Our participants are not ‘patients’! Certainly all potential participants must provide
written informed consent to take part before entering the study - this is a basic
requirement for ethics committee approval. This information was given on page 16.
Participants are provided with information about the research by one of the research
team, and they can take as long as they wish to make a decision about whether they
wish to take part. Once a participant has agreed to take part and provided written
consent, assessment sessions are arranged. All assessments are administered in a face-
to-face session with a researcher. All drop outs at whatever stage will be recorded and
reasons noted where these are available. Participants are of course free to drop out
without giving a reason. We have added this point on page 6.

Comment: The people that attend the community the resource centre may be selected
group that cannot be generalised to all older males and females, a group that may
need interventions that promote health aging and the reduction of emotional, physical
and social disabilities.
Question/s: Who attends the community resource centre and why?
An important aim of the feasibility study is to identify and profile the centre attendees
and their reasons for attending the centre. This information will be important in
developing a larger trial. This point has been added in the discussion on page 19.

Comment: I note that there is no upper age group included in the inclusion criteria.
The minimum age is 50 years. In Australia many in that age group are still working
outside the home earning and income. If the subjects recruited in this feasibility study
are mainly in the early 50s rather than late 70s end of the spectrum then the results
again are likely not going to be generalisable to older and males and females who I
assume are an important target population and on whom we would want evidence to
determine whether there are benefits from this program. Colloquially it is said that
the 50s are the new 40s and so forth, therefore if we want to be targeting an older age
group, this feasibility study could stratify the population into those between 50 and 65
and those 65 and over into equal groups across the three arms. If this feasibility study
concerns developing and testing interventions that can be used to promote healthy
ageing across a spectrum of the aged then these important design issue should be
addressed. If this is a feasibility study then subgroup stratification is not an issue for
sample size.
Question/s: Were the investigators planning to use stratification to deal with this
issue? If so could they describe? If not would they provide reasons for not doing so?
We have considered the issue of stratification by both age and gender and the
randomization process we implement does include stratification by gender. We have
added this point on page 7. Age Cymru Gwynedd a Mon operates 3 similar centres on
the Isle of Anglesey and experience with these shows that more women than men are
likely to attend. As regards age, we anticipate that most participants will be over 65
but there will be a small number of under 65s who may for example have retired early
for health reasons and for whom this kind of intervention may be particularly useful.
We have not stratified by age due to the relatively small sample size of this
development study, but we will look at age differences in the data if our sample
allows for this comparison. This point has been added in the discussion on page 19.

The final issue is whether a subjects recruited from a village apply to an urban, city
population, one where social isolation may be manifest differently. My concerns are
that the same generalisability issues may arise, if the main study included subjects
from communities that differ from Nefyn. From a quick Google search “With a population density of 46 persons per square kilometre, Gwynedd is the third most sparsely populated county in Wales. Gwynedd, being many a rural area, is characterised by small settlements scattered around the county and larger urban settlements centred around Bangor and Caernarfon in the north, Pwllheli to the west, Porthmadog and Blaenau Ffestiniog in the centre, and Tywyn and Porthmadog in the south. 48.5% of the population live in the former district of Arfon which includes the City of Bangor, Caernarfon, Bethesda, Llanberis and Penygros. In Gwynedd, the ethnic minority population is small at 1.2% non-white people. The largest single ethnic group in 2001 was Chinese. However, parts of Bangor has one of the highest proportions of ethnic minorities in Wales due to the presence of students from ethnic minorities studying at the University and medical staff recruited from abroad to work at Ysbyty Gwynedd.”

Question/s:
What is the population of village of Nefyn, Gwynedd? What is its socioeconomic profile?
The population of Nefyn is described by the ONS (2001) as: Total Population: 2,619; males 1244; females 1375; Number of households 1124. The socio-economic profile is as follows:

<table>
<thead>
<tr>
<th>All People Aged 16 and over in Households</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>AB</strong>: Higher and intermediate managerial / administrative / professional</td>
</tr>
<tr>
<td><strong>C1</strong>: Supervisory, clerical, junior managerial / administrative / professional</td>
</tr>
<tr>
<td><strong>C2</strong>: Skilled manual workers</td>
</tr>
<tr>
<td><strong>D</strong>: Semi-skilled and unskilled manual workers</td>
</tr>
<tr>
<td><strong>E</strong>: On state benefit, unemployed, lowest grade workers</td>
</tr>
</tbody>
</table>


Will the main trial include subjects from the same or different demographic?
There is a risk that interventions of the kind we are conducting end up accessing people from more advantaged socio-economic groups, and it is important to access people across the socio-economic spectrum. The socio-economic profile of Nefyn provides a good basis for this, with relatively high proportions in the C categories and significant proportions in the D and E categories. We anticipate that a larger trial would also seek to access a broad spectrum of individuals. Clearly in a development study that by its nature has to be located in one geographical area it is not possible to address urban/rural differences and to provide results that are universally
generalizable, and this will be acknowledged as a limitation. Our view is that providing interventions of this kind is likely to be more challenging in a rural area than an urban area because of issues with transport and accessibility, and therefore this provides a good test of the feasibility of our approach. This point has been added in the discussion on pages 18 - 19.

**Editorial Request:**

*Please include a section explaining your trial status. This should follow the Discussion section. The status of the trial at the time of manuscript submission. The journal considers study protocol articles for proposed or ongoing trials provided they have not completed patient recruitment at the time of submission.*

We have added the following statement to the MS:

**Trial Status:** This trial is currently recruiting. Recruitment commenced on 02 January 2012 and is scheduled to continue until 30 September 2012.