Phase one of a cluster randomised trial to prevent weight gain in women living in rural communities

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Background

Halting weight gain in those who are currently normal weight as well as those who are overweight or obese is one of the most critical public health priorities currently facing Australia (1, 2). Despite the recognised need, few weight gain prevention interventions in adults have been reported. Our group has previously developed a weight gain prevention intervention for women living in a metropolitan area (HeLP-her) which showed a significant difference between the intervention and control groups (adjusted -1.13 kg, CI -2.03 to -0.24) at one year and subsequently published in the BMJ (3). We have now adapted this evidence based program for delivery to women in rural communities. The primary aim of this HeLP-her rural project is to determine if a one year behavioural intervention prevents weight gain and improves health related behaviours in women living in small rural communities in Australia and if these behaviour changes are sustainable.

Alongside this large randomised control trial (RCT) we are conducting a rigorous economic and community evaluation of the HeLP-her rural program. Best practice principles for community-based obesity interventions outline the integral role of evaluation in translating successful interventions into clinical practice (4). Additionally, the evaluation will explore barriers and enablers to implementation, the influence of the program on the broader communities’ health behaviours, stakeholder’s and participant satisfaction with the program and determine the rural community’s interest in sustaining the program. Community evaluation is important in this project, as whilst the importance of implementation and evaluation research has been established, few large scale community intervention studies have prospectively incorporated an evaluation strategy. Here we describe the recruitment and delivery of the trial as well the evaluation plan.

Method

The HeLP-her rural study will utilise a cluster randomised controlled trial design to prevent weight gain in a population of reproductive-aged women living in rural Victorian communities. The study is being conducted in rural Victoria, across 34 rural shires. We aim to recruit 840 women from 42 town (population 2,000-10,00) clusters of 15 women and 21 of these communities will receive the intervention, whilst 21 communities will act as control groups.

A comprehensive communication plan has been developed to communicate with and develop collaborations with local organisations. Communication has occurred at the Government regional level, Local Government, Primary Care Partnerships, local health and education sectors as well as community organisations. The primary method of recruitment has been through schools, kindergartens, day care, and sporting clubs. We use local media to raise awareness of the program and make a personal visit to every town to connect with the local community. The primary school is most frequently approached to provide a venue.

The 1-year intervention is designed to be low intensity and therefore low cost, with a focus on self-management, clear messages on physical activity and healthy eating, small sustained changes to behaviour. Delivery includes one face to face group event and one phone coaching event as well as monthly contact by mobile phone SMS. The intervention is followed by an observation year to determine sustainability of program outcomes.

The community evaluation involves both a process and summative evaluation and will employ a mixed methods approach. The RE-AIM framework will be utilised to guide this evaluation, which will address the Reach, Efficacy, Adoption, Implementation and Maintenance of the HeLP-her Rural program (9).
Semi-structured interviews will be conducted with participants and local key informants such as local government workers, health workers and school principals, observations and focus groups.

The primary outcome of HeLP-her Rural is the difference in weight gain between the control and intervention groups. Secondary outcomes include dietary intake (5) physical activity, (6) self-management behaviours, self-efficacy, (7) and quality of life (8). In addition we will explore a range of outcomes including changes in knowledge, attitudes and behaviours following the intervention and barriers and enablers to implementation.

Results
As of March 2013 we have recruited 510 women from 35 rural communities and delivered the baseline program. We plan to complete the program recruitment and delivery phase of this program by the end of April 2013. We have engaged over 140 primary schools and kindergartens across communities as well as numerous community organisations and media. The uptake and support by school principals and kindergarten directors has been very positive and the support and collaboration with local organisations has contributed to the success of recruitment.

Discussion
Community prevention interventions in real life settings are complex and challenging to deliver. To our knowledge this is the largest lifestyle related randomised controlled trial in adults in Australia and the learnings from this project will impact on population weight gain prevention strategies nationally. Through the development of a comprehensive communication strategy, collaboration with local communities and incorporating a rigorous evaluation strategy we will capture significant detail on the implementation methods and generalisability of this program, as well as exploring issues surrounding the feasibility, efficacy, interest, participation, delivery, cost and sustainability of the HeLP-her Rural program. If, as appears likely, we can prevent weight gain with a simple intervention which proves to be cost effective and can be delivered easily to most women in Australia, we can make a significant contribution toward preventing the predicted upward shift in population weight and the consequences of obesity related illnesses (10).

References
