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THE *Change*
PROGRAM

The Change Program

**A pilot implementation trial
of a general practitioner-
delivered weight
management program in
primary care**

Elizabeth Sturgiss, Kirsty Douglas, Nicholas Elmitt

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Australian Primary Health Care Research Institute

The Australian National University

Acton ACT 0200 Australia

E change.program@anu.edu.au

<http://www.changeprogram.com.au>

<http://www.health.act.gov.au/professionals/academic-unit-general-practice>

<http://medicalschoo.anu.edu.au/research/academic-unit-general-practice>

Contents

Background.....	4
Obesity as a health problem	4
Current approaches and guidelines	4
Why General practitioners should be involved	5
Prior work leading to this pilot	5
Aims of this pilot	6
Methods	7
Analysis	9
Results.....	10
Recruitment	10
Patient demographics.....	10
Drop-out rates	11
GP CONSULTATIONS	12
Acceptability	13
Feasibility	15
Feedback on The Change Program materials	19
Trend to effectiveness	20
Discussion.....	22
Refinement of protocol.....	22
Refinement of program materials.....	23
Timeframe development	24
Hypothesis for effect.....	24
Conclusion.....	24
References.....	26

Background

OBESITY AS A HEALTH PROBLEM

Overweight and obesity are global health challenges currently estimated to be responsible for 2.8 million deaths each year and an estimated loss of 35.8 million disability adjusted lost life years (DALYs).¹

The metabolic changes associated with overweight and obesity include adverse changes in blood pressure, triglycerides and insulin resistance with increased risks of coronary heart disease, ischemic stroke and type 2 diabetes mellitus. In addition, obesity increases the risk of cancer of the breast, colon, prostate, endometrium, kidney and gall bladder. Overall mortality rates increase with increasing degrees of overweight.²

In Australia, approximately 63% of adults are overweight or obese according to 2012 statistics, which is a 10% increase compared to 1995, while 25% of children are overweight or obese.³ Data for Australia and the surrounding region reveal that high Body Mass Index (BMI) is the second greatest contributor to burden of disease after nutritional risks.⁴ Obesity and its consequences are not distributed evenly throughout the population; they are more prevalent amongst lower socioeconomic groups, Aboriginal and Torres Strait Islander peoples and those in rural and remote areas of Australia.⁵

In 2005, The Australian Diabetes, Obesity and Lifestyle estimated total direct costs for overweight and obesity at \$21 billion⁶ and indirect costs at \$35.6 billion per year.⁷

CURRENT APPROACHES AND GUIDELINES

Reversing the rising prevalence and consequences of obesity requires complex multi-level responses. The complexities and domains of necessary action are well illustrated in the Foresight obesity system map.⁸ Whilst broad societal change is sought there is a continuing need to optimise care and management of those individuals already overweight or obese.

In 2010, the National Health and Medical Research Council (NHMRC) commissioned the development of clinical practice guidelines for the management of overweight and obesity in adults and these were updated in 2013.⁹ These guidelines are intended for use in primary care and advocate multidisciplinary management including referral outside the general practice environment. This endorsement of multidisciplinary management reflects the majority of the evidence that assesses interventions in primary care delivered by allied health or trained lay advisors with variable success.^{10, 11}

Although multidisciplinary care is currently the preferred framework for the overweight and obese patient, for a variety of reasons this is not available to every patient. Location, in particular rural and remote communities, cost, patient time pressures and preference are just a few of the reasons patients may request to see their GP for ongoing weight management.^{12, 13}

Remarkably little research has trialed formal interventions delivered by primary care doctors. There has only been one international randomised controlled trial in which a primary care doctor delivered an intervention to overweight and obese adults conducted in the United States of America.¹⁴ This study showed a small benefit in the treatment arm at six months.

WHY GENERAL PRACTITIONERS SHOULD BE INVOLVED

Access

GPs are the entry point for government funded healthcare in the Australian health care system, and access is high. The Australian Patient Experiences survey found 86% of those aged 15 years or more visited a GP at least once per year. Between 30-40% of all people aged under 75 saw their GP four or more times a year and, in the over 75 age group, nearly 25% visited their GP 12 or more times a year.¹⁵

Respect

Most Australians identify a regular GP or general practice thus providing good continuity of care.¹⁶ The Australian Bureau of Statistics (ABS) patient experience data shows that of those who had seen a GP in the previous 12 months, over 70% reported that the GP always listened carefully to them, always showed them respect and always spent enough time with them.¹⁵ Australian GPs enjoy high rates of patient satisfaction.

Acknowledged role

In a survey of NSW general practices, 78% patients (n=227) thought their GP did have a role to play in weight management and 78% were also keen on regular review with their GP.¹²

Appropriate training

Although recently challenged by major cuts and reorganisation, prior to 2015, GP training in Australia had been internationally recognized for its quality. The structured education and supervised practice in the five domains of: communication skills and the patient-doctor relationship, applied professional knowledge and skills, population health, professional and ethical role, and organisational and legal dimensions ensure that GPs have skills which allow them to engage effectively on an individual level with the biopsychosocial antecedents of obesity.

Low cost to patient

Currently over 85% of all GP consultations are bulk billed and therefore the patient incurs no point of care cost.¹⁵ Allied health services such as dietician services and exercise physiology are only subsidized in the context of a chronic disease management plan for which presence of comorbidity (e.g. diabetes, cardiovascular disease) are required. Uncomplicated overweight or obesity does not qualify for subsidised services in allied health.

PRIOR WORK LEADING TO THIS PILOT

This work was initiated by practicing GPs who were working with patients that did not want multidisciplinary referral but could find few functional tools available to assist them.

The NHMRC Clinical Practice Guidelines for the Management of Overweight and Obesity in Adults, Adolescents and Children in Australia is a thorough distillation of current research evidence but it is 232 pages long making it indigestible in the clinical setting particularly given the amount of material sent to GPs.¹⁷ The full NHMRC guideline has been distilled into a seven page document for GPs that is based around the “5 As” – Ask, Assess, Advise, Assist and Arrange.⁹ However, even this guideline does not provide tools or specific advice for GPs to use within consultations.

The driver for this project was to provide GPs with practical advice and tools to use in their consultations with patients with whom they were addressing overweight and obesity.

In the first stage of the work, current Australian clinical practice guidelines that addressed overweight and obesity were reviewed and synthesised.¹⁸ The synthesis was structured around five themes of: logistics, measurement and assessment, lifestyle (including behavioral interventions and awareness of cultural issues), nutrition, and physical activity.

The second stage was to develop a practical tool that incorporated the principles of the guidelines into a functional handbook that could be utilised by GPs and their patients in daily practice. This weight management program was based on current evidence and was collaboratively designed with input from practicing GPs, a dietician, psychologists, and consumers.¹⁹ The resultant program, The Change Program, fits into the “Assist” and “Arrange” stages of the NHMRC guideline and should promote translation and uptake of the guideline principles.

AIMS OF THIS PILOT

This implementation pilot study aimed to evaluate the feasibility of a GP-delivered weight management program for overweight and obese adults in primary care (The Change Program), and its acceptability with patients.

This pilot had a number of aims including,

1. Feasibility of a GP-delivered weight management program in primary care
2. Acceptability of such a program to both patients and GPs
3. Refinement of a future RCT protocol by exploring recruitment processes, dropout rates and timeframes.

This pilot study involved a range of GPs, both urban and rural, implementing The Change Program with their patients. The aim was to receive qualitative and quantitative feedback from the GPs and the patients regarding the utility, practicality and implementation of the program. Following successful completion of this study we will seek funding to conduct a cluster randomised controlled trial of The Change Program in primary care.

Methods

This pilot implementation trial involved five practices, four urban and one rural. It was a single arm intervention trial that will be the “intervention arm” of a future randomised control trial. The ethical aspects of this trial were approved by the ANU Human Research Ethics committee and the trial was registered before recruitment commenced (ACTRN12614001192673).

The Change Program was designed as a GP-delivered weight management program for patients who are overweight or obese and at risk of developing chronic illness associated with obesity. The program was intended to be undertaken between a patient and the GP that they usually see. The program draws on the four pillars of general practice being first point of contact, whole person, patient-centred, and continuous care. The GPs were given a suggested consultation schedule that was based on the NHMRC guidelines and were asked to see patients every fortnight for the first three months, then every 4-6 weeks for the following three months. They were asked to continue to assess the patient for relapse and intensify appointments as necessary.

The Patient Workbook holds a number of factsheets and also practical worksheets that require the patient to reflect on different aspects of their current lifestyle. The worksheets do not all need to be done in session, but can be completed by the patient at home and used to aid discussion with their GP. The Program also encourages the ongoing recording of the following data: BMI, waist circumference, blood pressure, relevant biochemical profile as well as a patient well-being score. The GPs were not given any instruction as to whether the consultation should cover other patient health problems during a weight management consultation.

The GPs were recruited from an email invitation and any GP that elected to be involved was asked to recruit at least one other GP from their practice. GPs were eligible to participate if they worked on at least one day per week at the enrolled practice and were fully qualified. GP Registrars were not eligible for recruitment. A member of the research team met with each GP to gain formal consent, explain the research processes and method for recruiting patients. Table 1 shows the practices and the spread of the GPs recruited.

Table 1 – Characteristics of GPs recruited for the pilot

Practice Location	Total number of GPs in practice (not equivalent to FTEs)	Number of GPs recruited	Experience of GPs recruited in years
Urban	8	3	4, 21, 30
Urban	10	2	10, NR
Urban	7	2	5, 9
Urban	10	3	4, 12, 11
Rural	9	2	7, 23

NR = not recorded

The 12 GPs were recruited within four days of a call for interested participants. Some of the GPs we collaborated with to write the program materials also expressed interest in participating in the pilot, and some were recruited this way. Additionally, we were contacted by a local community newspaper who ran a story on our background work, which familiarised GPs with the work we planned to undertake.

GPs were given the recruitment information to recruit their own patients. They were asked to offer the opportunity to any patient who met the eligibility criteria. They were given a checklist as part of the patient recruitment pack to determine patient eligibility. GPs were offered promotional posters to put in their waiting room to assist with recruitment. The research team were in regular contact with the GPs to assist with recruitment as needed. Patient eligibility criteria included,

- > adult over the age of 18 years
- > English speaking and reading
- > BMI > 25 and ≤ 40
- > visited the GP at least three times in the last 2 years
- > no past or scheduled bariatric surgery
- > Australian Type 2 Diabetes Risk Assessment Tool (AUSDRISK) score of 6 or more

Patient exclusion criteria were:

- > any uncontrolled medical or mental health condition
- > current history of diabetes, congestive heart failure, chronic renal failure or chronic obstructive pulmonary disease
- > significant immobility
- > history of an eating disorder
- > pregnant or breast feeding
- > age over 65 years
- > taking weight loss medications

The GPs were provided with “The Change Program” materials that included the GP Handbook (40 pages of reference material), Patient Workbook (64 pages of patient information and worksheets) and a computer template that had some interactivity with their desktop software. The computer template had spaces for the GP to enter information about the patient’s motivation level, anthropometric measures, goal setting and review and documentation of any factsheets specifically referred to.

Initially all GPs were interviewed with information collected on the GP’s current management plan for patients who are overweight or obese, their confidence in managing patients with obesity as well as the barriers and facilitators they experienced in this management.

Patients were asked to complete online surveys at base line, three months and six months. These surveys included general questions about their relationship with their GP (time zero only), and their experience of the program (time three months only) as well as a Binge Eating Scale (all three time points), Impact of Weight on Quality of Life -- Lite (all three time points), Physical Activity Scale and the WONCA-COOP Quality of Life scale.

GPs were asked to complete an online survey of their recruitment experience once they had completed their patient recruitment. This questionnaire covered details about how many patients they suggested the pilot to, whether they suggested the program or if the patient asked for assistance with weight loss, and whether they would consider alternative recruitment options (eg via reception staff, or through a research officer). At the end of the pilot intervention they were also asked to complete the NoMAD survey, a new quantitative tool for measuring aspects of Normalisation Process Theory.²⁰ Normalisation Process Theory is an Action Theory that gives a framework for evaluating the implementation of complex interventions. All online surveys were collected using Qualtrics software.

At the completion of their six months of the intervention all GPs and patients were offered an interview. Patients who formally withdrew from the intervention were offered an interview at that stage. These interviews were based on Normalisation Process Theory to assess the feasibility and acceptability of the intervention. The research team conducted interviews by phone or in person, depending on the participant’s preference. The participants were also

asked about any suggestions they had for improving the program materials and the overall process.

The research funding covered the cost of appointments for the patient. The GPs submitted invoices for each consultation to the research team and were paid \$65 (excluding GST) for any appointment less than 20 minutes, and \$120 for any consultation over 20 minutes. This payment was allocated based on the average consultation cost in practices in our region. It was less than usual costs for the urban practice but more than usual costs for the rural practice. The patients were aware that their consultation costs would be covered by the research funding.

ANALYSIS

All interviews were audio-recorded and transcribed verbatim. Deidentified texts were analysed using informal thematic analysis based on the topics of interest for our pilot. Our themes were: acceptability, feasibility, confidence, defining success, the GP role and relationship, practicalities of the workbook, suggestions for improvement and influencing others in the patient's life.

Details of each appointment were collected from the computer template, coded using the patient's Study Identifier and entered into a Microsoft Excel document. The Qualtrics data regarding the online surveys was also transferred into the excel document using the patient's Study Identifier. This pilot implementation trial was not powered to find out whether The Change Program was effective in assisting weight loss. For this question to be answered, we would need a much larger trial. With this in mind, we used linear mixed models and generalised linear models to assess whether there was any trend to effectiveness in this small sample size (SPSS).

The NoMAD survey completed by the GPs at the end of the pilot gave an overview of the implementation complexities with this pilot intervention.

Results

PATIENT RECRUITMENT

Patient recruitment proved more difficult. Each GP was asked to recruit two patients and this took longer than anticipated. One GP elected to recruit only one patient as they found the process too time intensive. Another GP did not recruit any patients as they were on leave during the recruitment period. The two patients allocated to that GP were recruited by the other GP in the practice.

Patient recruitment issues that were identified included:

1. **Time:** When running late GPs did not look to recruitment as it would further delay their waiting patients.
2. **Cost:** Some GPs waited for specific disadvantaged patients to attend as they wanted them to benefit from regular, fully subsidised appointments.
3. **Familiarity with GP:** Patients were recruited by GPs who were actually a regular patient of another GP in the practice because their usual GP was not participating in the pilot.
4. **Selection Criteria:** Finding a patient with a BMI below 40 as one of the inclusion criteria made it more difficult to recruit as some interested patients had a BMI just over this limit. This was communicated to the research team and some patients were enrolled who had a BMI of up to 42. GPs also recorded that it was difficult finding an eligible, motivated patient without diabetes.
5. **GP's willingness to discuss:** GPs on average only discussed the research opportunity with a small number of patients.

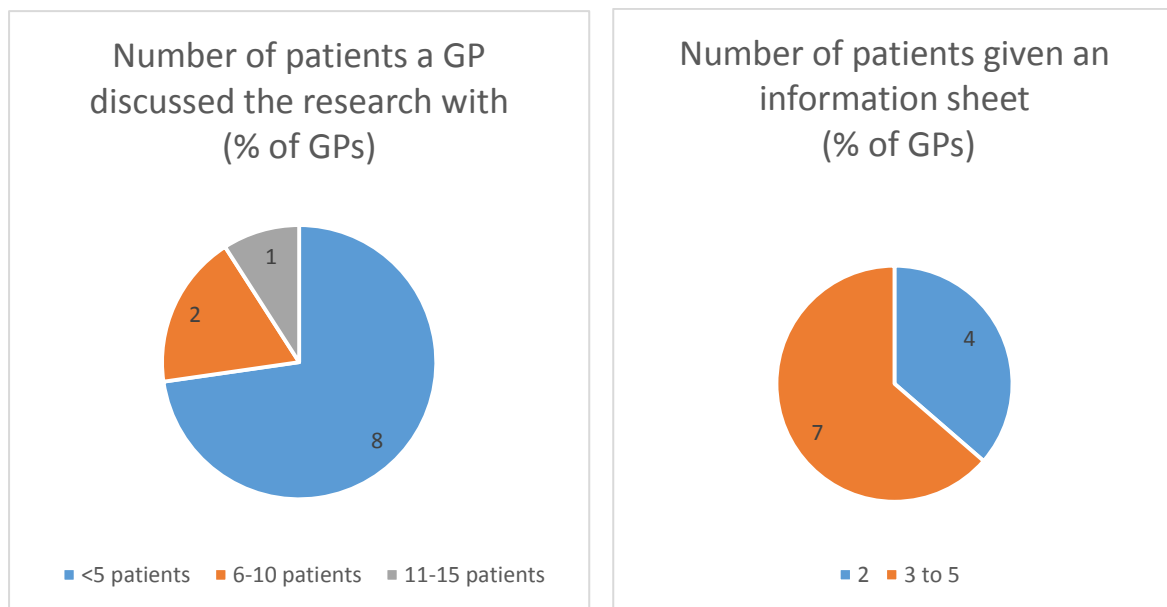


Figure 1 – Recruitment of patients by GPs

PATIENT DEMOGRAPHICS

Twenty-three patients were enrolled in the pilot implementation trial. The basic demographic information is given in the figures below. In addition, the patients had all experienced various

attempts at weight loss in their life. All but a few had used a commercial weight loss provider on at least one occasion, some had used weight loss medications and most had tried a physical activity program through a gym or similar provider.

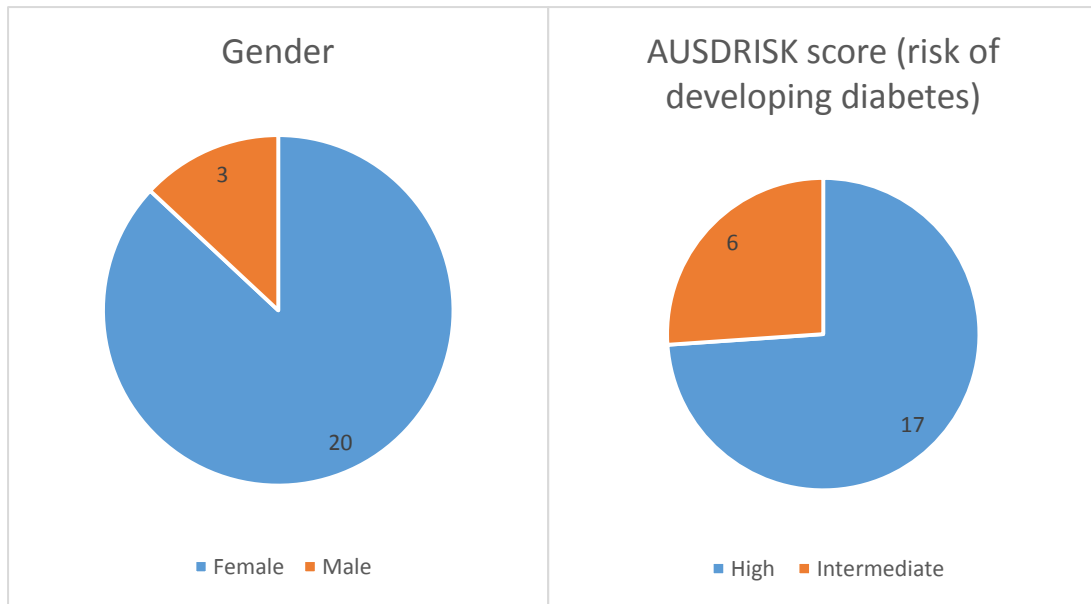


Figure 2 – Patient demographics (n = 23)

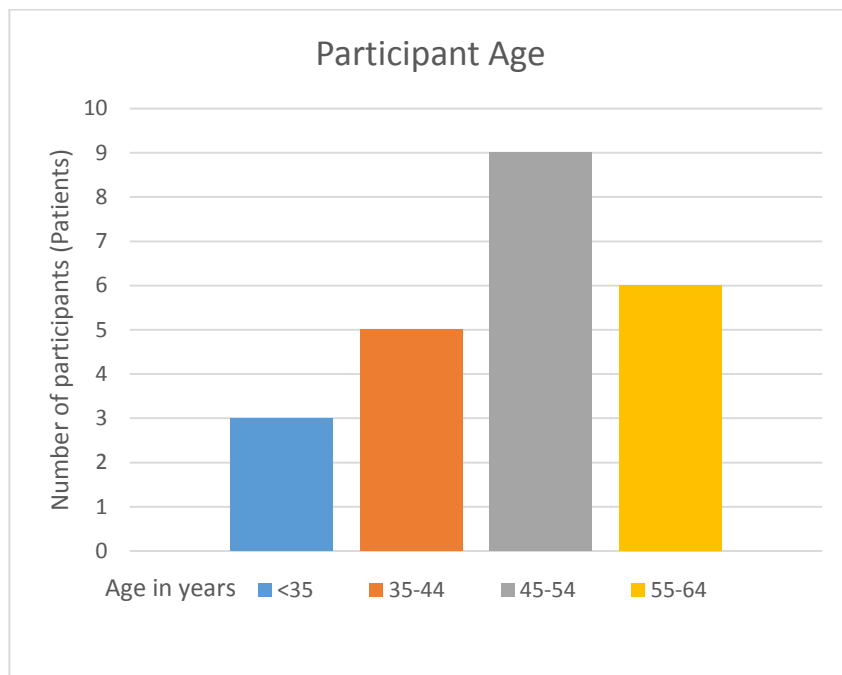


Figure 3 – Participant (Patients) Age

DROP-OUT RATES

By three months, three patients had formally withdrawn from the study. In addition to these three withdrawals, a further three patients had a total of three or fewer appointments with

their GP. Of this second group of three, two completed an interview and surveys at six months and one was unable to be contacted at the end of the pilot.

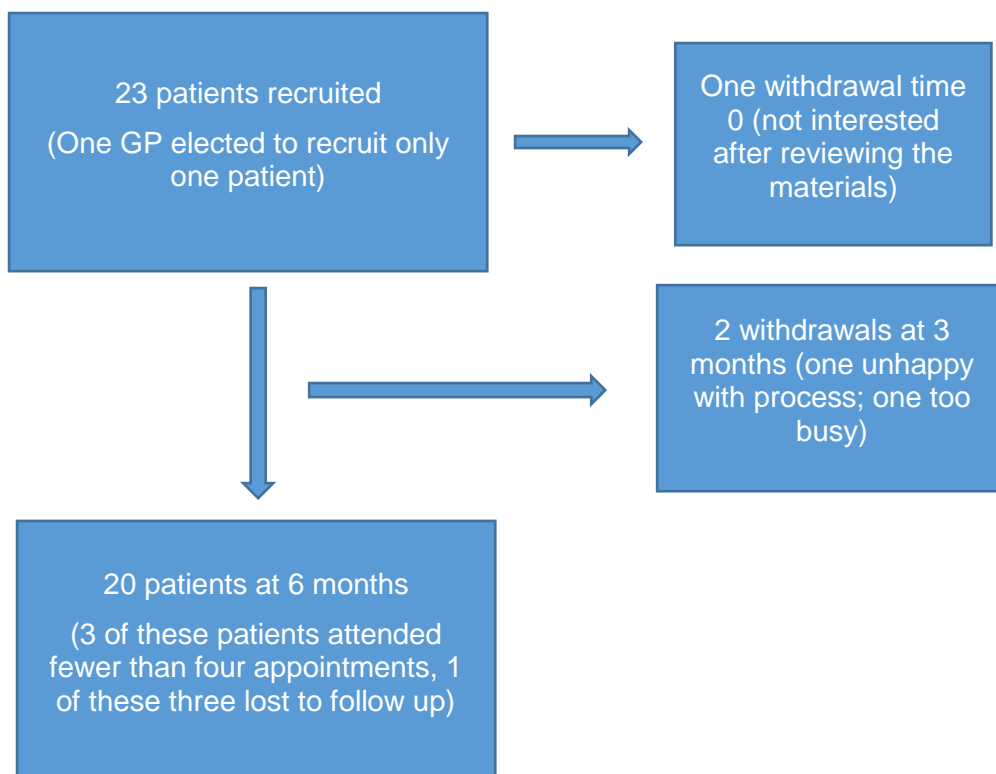


Figure 4 – Patient recruitment flow chart (n = 23)

GP CONSULTATIONS

The average consultation time was 23.6 minutes, ranging from 11 to 60 minutes.

Each patient attended an average of six consultations across the six months. However excluding the six patients who attended fewer than four appointments or withdrew, each of the remaining seventeen patients attended an average of eight appointments.

The GPs were not specifically asked to collect data relating to things discussed in the consultation apart from weight management. This being the case, all the available information may not have been collected, but on 44 occasions it was identified from the template that another health condition was discussed and managed by the GP. Conditions ranged from upper respiratory tract infection symptoms through to post hospital care for an acute admission. Preventative care was undertaken (e.g. cervical screening, osteoporosis screening) and social stressors were discussed. This was in keeping with whole person care – one of the pillars of general practice.

The GPs reported applying the program materials in a way that best suited their patient, focussing more on nutrition or physical activity depending on the patient's history and needs.

I can't say I was very strict in terms of using the worksheets when it was recommended. Some of them we didn't use because we didn't feel it was necessary, the patient had a good handle on that but it was just wonderful to have the opportunity to catch up frequently and I think that was helpful. (GP 94F)

I mean I was pretty flexible with them in terms of what they did and didn't, because I didn't want to say you must. I didn't want to be prescriptive and say you must do this, and then when they don't do it they've failed. And that's sort of, for me that's not so helpful. (GP 24B)

The other phenomenon recorded by the GPs was on two occasions two different GP did not take the anthropometric measures of the patient as they noted the patient was acutely distressed. This displays the patient-centred approach that is central to general practice care.

ACCEPTABILITY

At the three-month time point, the patients were asked to complete an online survey to assess acceptability mid-way through the pilot. As can be seen from the chart a majority of the patients were finding the program helpful and would recommend it to a friend. At six months we asked some general questions of the GPs and asked them to give a score out of ten, where ten is definitely agree and the responses are seen in the chart below.

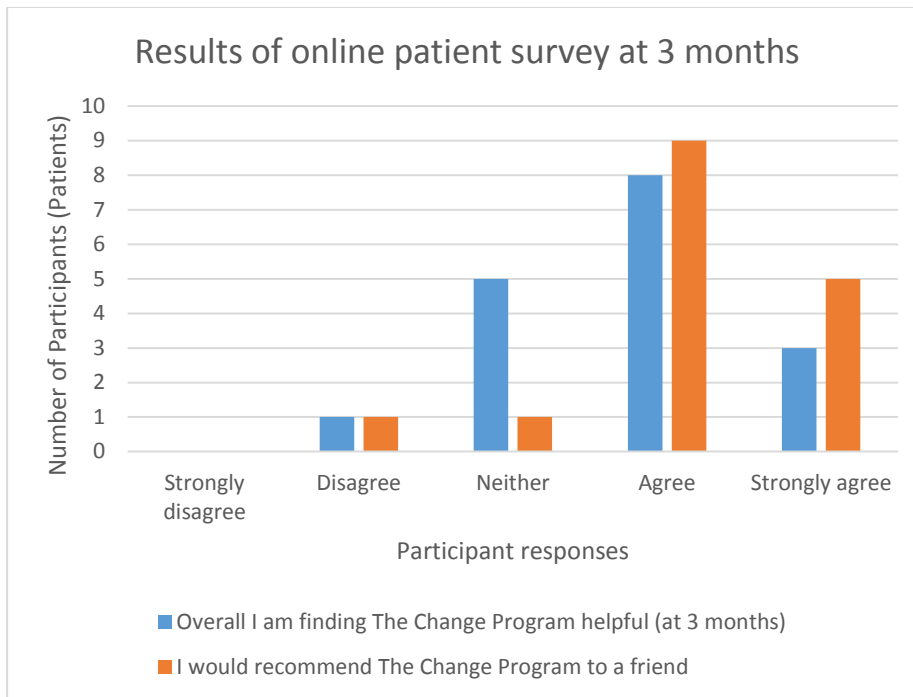


Figure 5 – Results of online patient survey at 3 months

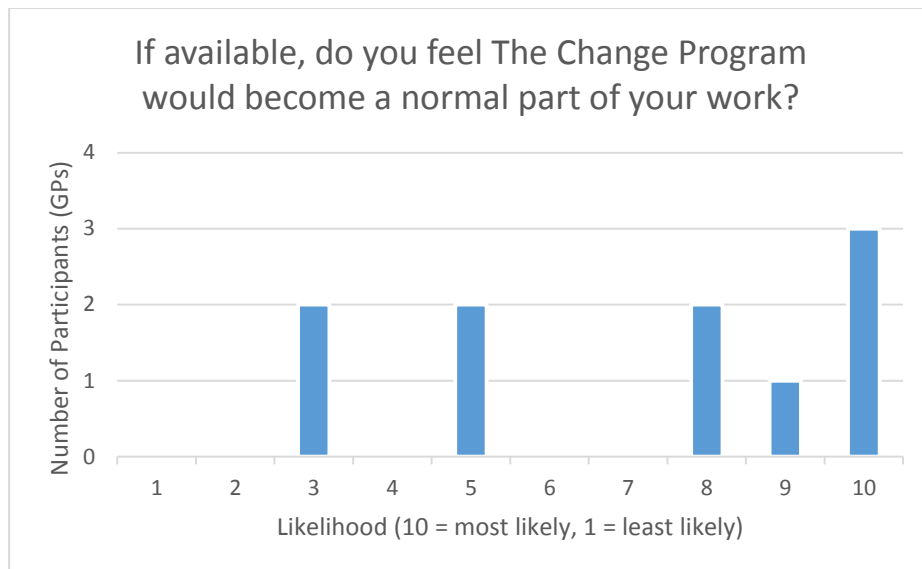


Figure 6 – GP responses to acceptability questionnaire

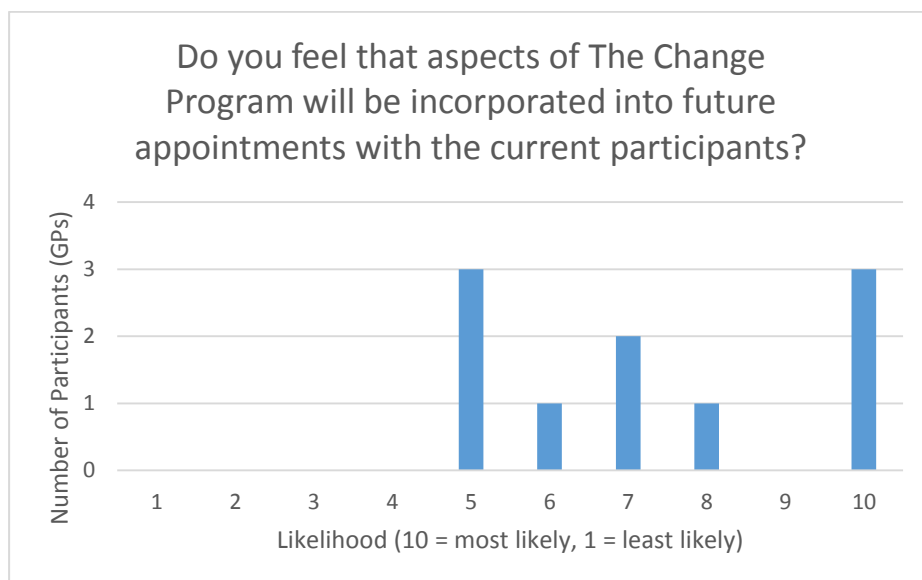


Figure 7 – GP responses to acceptability questionnaire

In the six-month interviews, almost all of the GPs and a majority of the patients found The Change Program a very acceptable concept.

I really enjoyed it; I think it's been fantastic....I think it is realistic and completely achievable and I feel incredibly optimistic. I will be continuing, I'm going to make an appointment over the next two or three months and I will continue until I hopefully reach my goals. (Patient 20)

I've enjoyed it, I just needed something, I needed another way. I've done Weight Watchers and I've done the gym and... but it was always fairly quick and then I'd put weight back on. (Patient 22)

It was good. It was good to have a structure. (GP 22A)

Interviewer: Do you think you would choose to use this particular Program with patients in the future?

Yes I would. I would. Because it's nice to have... I'm a fan of the handout, and it's nice to have something to give people. Yeah. I would. For sure." (GP 24B)

GP Relationship

The relationship with their GP was a particularly important aspect of the program for many of the participants. Participants reporting a stronger relationship with their GP attended more appointments and have stayed in the program for a longer length of time.

Interviewer: Do you think working with your GP was important?

Crucial. Yeah. For me, and it's different for people, as I said for me the main thing was, as I said, I didn't want to feel like I'd let him down, although it was myself that I'm letting down. That's silly to think that way, because if I didn't succeed it's only letting myself down. But I didn't want to go there and feel that he was, you know that this was a waste. I wanted to make it succeed for that reason. (Patient 3)

In contrast, the patients who had withdrawn or attended three or fewer appointments (total of six patients, 26.1%) were less favourable about the program overall.

I don't think I found it particularly useful. It was useful in terms of I had, you know, the sort of fortnightly goals to work toward, but I didn't find the program itself particularly useful. Put it this way, if my doctor had said, "Come and see me every fortnight and we'll see how much weight you've lost," it would have been the same thing. (Patient 5)

GP Role

A small number of patients who expressed guilt about seeing their GP for the program and felt they were overusing the GPs time. These patients stated they would have preferred to see the practice nurse to complete the program.

I must admit I felt frequently embarrassed that I was taking up a lot of my GP's time.... for me I think going to see the nurse would have been probably slightly more comfortable. I wouldn't have felt as guilty because I know that in some practices the nurses are only part time. (Patient 8)

One of the patients withdrew at the start of the program as they read the patient workbook and felt there was no information in the book that they didn't already know. This patient also felt that the role required of the GP in the program was not within a GP's scope of practice.

To me a GP is a sort of a, the one stop shop of OK where do we go from here, you know if you've got something serious you go elsewhere. They're the junction for referring you to different places and people. (Patient 17)

FEASIBILITY

We used the NoMAD instrument with the GPs to determine the feasibility of the intervention in day-to-day practice. This was given to 11 GPs, as one GP had not recruited any patients and would not be able to comment on the functioning of the program. NoMAD, a new quantitative assessment tool previously discussed, is split into four parts:

1. Coherence

This item reflects the GPs ability to make sense of The Change Program as they tried to operationalise it within their daily practice.

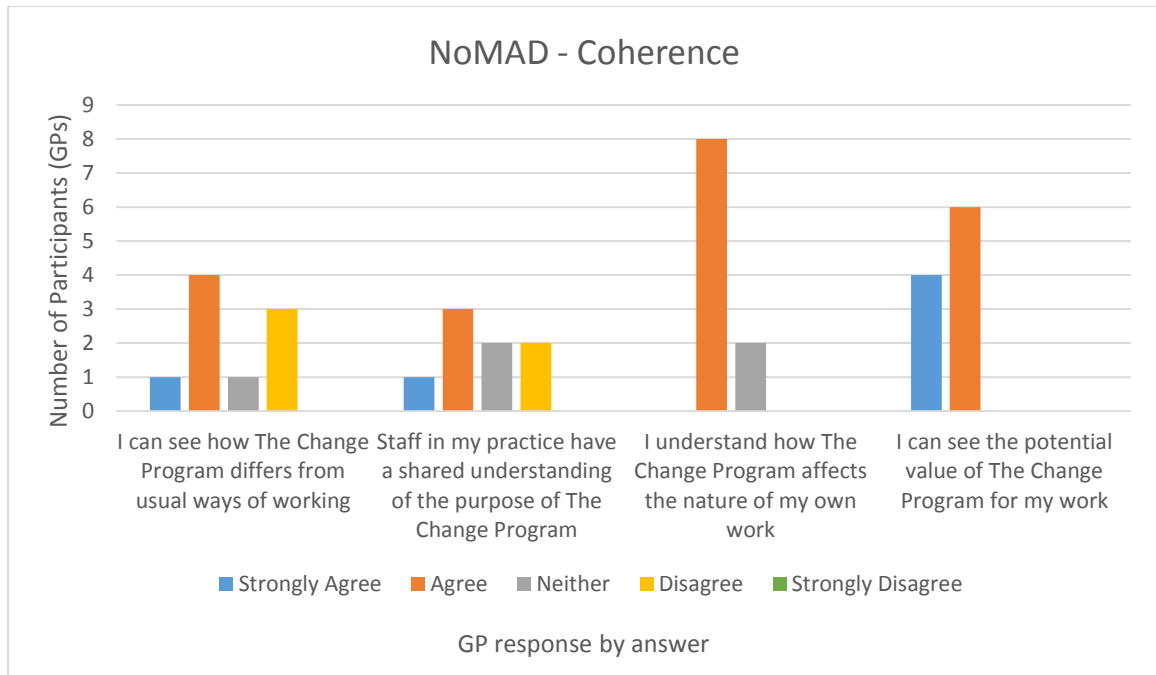


Figure 8 – GP responses to feasibility questionnaire

The GPs all saw the potential value of the program in their work. As we recruited GPs directly and did not involve the rest of the practice in implementing the pilot, only four out of the 10 GP respondents thought the staff in their practice had an understanding of The Change Program.

2. Cognitive Participation

This item aimed to assess the way the GP built a community of practice around The Change Program using relationships within their practice staff and whether they saw it as part of their role.

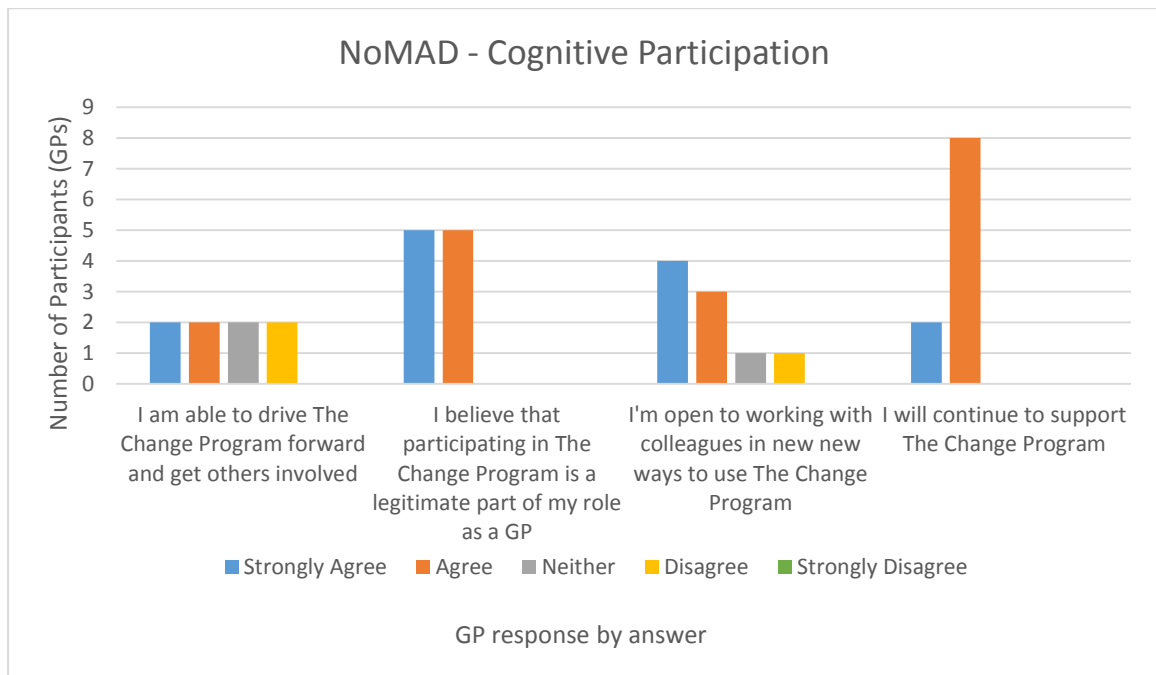


Figure 9 – GP responses to feasibility questionnaire

As we recruited GPs directly and did not involve the practice as a whole, the answers were reflective of low level of involvement of other staff in the practice. The GPs were able to see the program as a legitimate part of their professional role and all said they would continue to support the program.

3. Collective Action

This item assessed the way GP felt The Change Program was organised within their day-to-day work and the preparation for implementation.

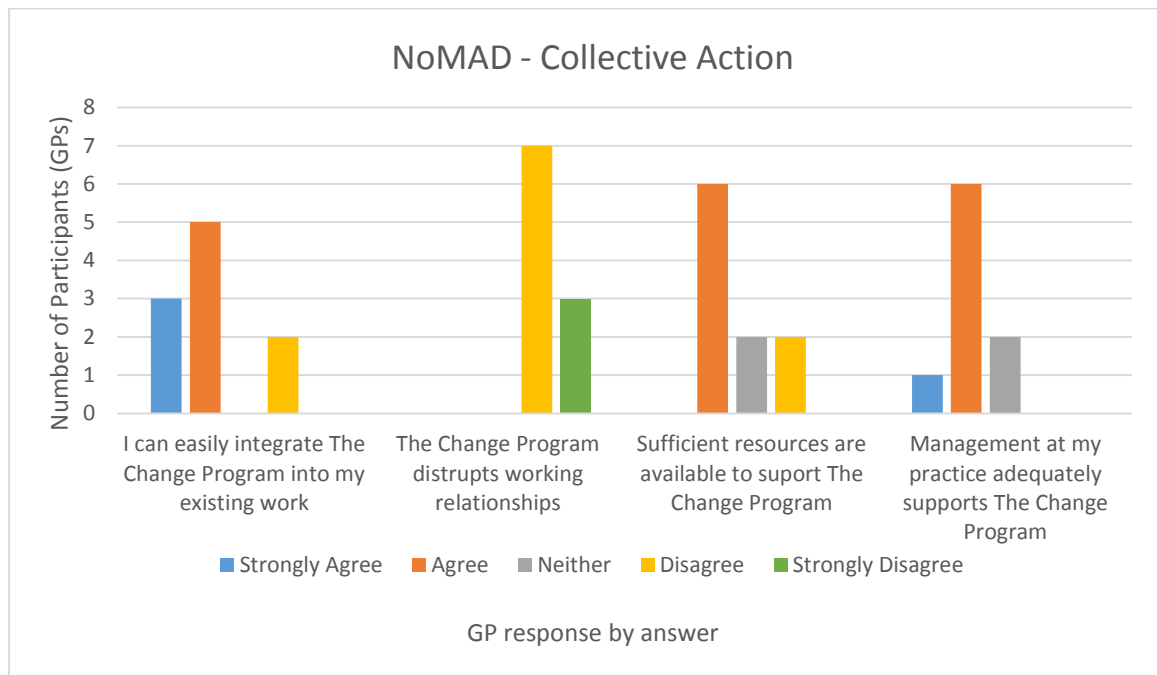


Figure 10 – GP responses to feasibility questionnaire

The GPs agreed that the program was able to be integrated within their work and was appropriate for their skill set. They were less sure about whether other GPs in their practice would be able to perform the work required in The Change Program and about half felt that further resources and training were needed to implement the program.

4. Reflexive Monitoring

This item asks GPs about their experience of evaluating the program and their role in it as the pilot progressed.

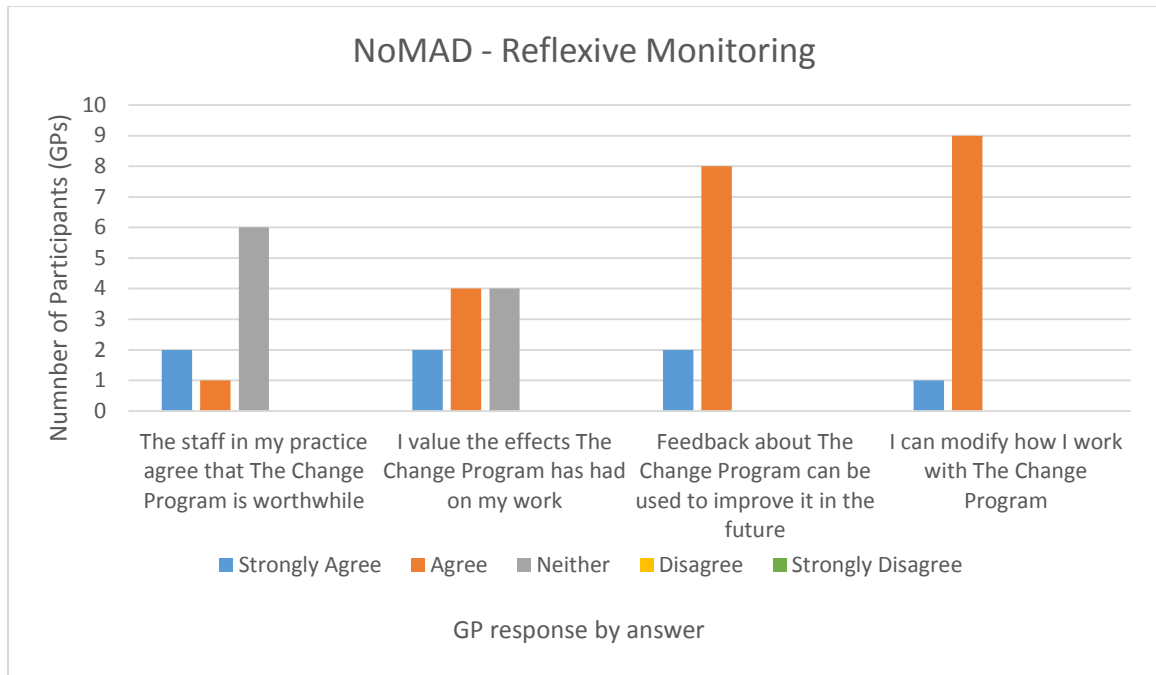


Figure 11 – GP responses to feasibility questionnaire

The GPs were not sure that the staff in their practice felt the program was worthwhile but there was strong support for using feedback for improvement and modification of implementation.

In terms of feasibility of timing for outcome measures the following table outlines the response rate for the various data collection at each time point:

Table 2 – Outcome measures over time

	Interview time 0	Online survey time 0	Online survey post recruitment	3 month online survey	6 month online survey	6 month interview
Patients	NA	22/23	NA	17/20	15/20	15/17
GPs	12/12	NA	11/12	NA	10/11	11/11

Cost

The appointment costs were covered by the research funding for this pilot. The main concern from patients regarding longer-term feasibility was their potential future out-of-pocket costs associated with continuing the program. Most patients when asked said that the full cost of appointments with a GP would prohibit them from participating in such a program outside a research setting. Interestingly patients did not take into account any Medicare reimbursement when considering cost of seeing their GP.

Interviewer: If you'd had to pay for them yourself, do you think that would have changed things?

I guess it would have changed the frequency of going in. Like but when you had to go in fortnightly, I probably wouldn't if I had to pay for that myself, I wouldn't have done it fortnightly, I would probably do every six weeks or something like that.
(Patient 7)

Time

A few patients felt that getting time out of work could be problematic. And others noted that it can be difficult to get an appointment with their GP which might affect feasibility.

Doctors tend to be rare entities for being able to get to appointments with, though she was good. I mean, it was probably... I mean, I think the last appointment I had to cancel it because of work and then of course, as would be the case, work cancelled the trip that they were sending me on, so it was irrelevant and I could have done the appointment. I was not happy. (Patient 18)

Each GP was asked at the six-month interview how many patients they felt they could manage on The Change Program at one time. Most said that they could start five or less at one time point with one GP feeling there would be no limit as it would become part of usual practice.

FEEDBACK ON THE CHANGE PROGRAM MATERIALS

We received a lot of helpful feedback from both patients and GPs as to how the program materials could be improved. In particular the ordering of the worksheets in the patient workbook meant that many patients did not see the behavioural interventions worksheets as they were located behind the "Relapse Prevention" tab. A few patients found the book too heavy and too large for carrying around during the day.

Many patients and GPs requested more information on nutrition with ideas for quick and healthy meals the most popular request.

I'd probably like to, you know if I... is the simple ways that you can knock up a quick lunch is probably the... I mean lunch is the killer for me. (Patient C)

Perhaps in practical nutrition, so it was very general, the nutrition aspect of things. Which is good, but maybe even some practical things there, or even some resources to... recipes for example, or types of food, or menu plans, that sort of thing would have been helpful for people. So it doesn't necessarily need to be in there, but perhaps links towards some choices. 'Cause that is something that people do struggle with. I think that they don't always know this aspect of things, sort of what the food is that they're eating, what it's worth. (GP 23J)

The factsheet on "Why is it so hard to lose weight?" that describes hormonal changes and weight plateauing was warmly received by the patients. However, some patients reported that they missed this sheet as it was hidden behind the introduction tab.

This is the most helpful piece of information I have read about weight loss in a long time! It helps explain some of the yo-yo results in weight loss/gain!
Thanks. (Patient 8)

GPs had a number of suggestions about the patient workbook. Some felt it would be better to split the book into factsheets and worksheets, and other would have preferred to give out each section individually over the course of the program. The computer template was not used by two of the GPs as they didn't realise they had it available. Most of the other GPs would have preferred the template to be more interactive with their desktop software, this is a challenge for any intervention implementation due to the number of different software systems available.

TREND TO EFFECTIVENESS

From the qualitative data we are able to deduce a number of aspects of change for both the patients and GPs. Many of the patients noted that they had seen a change in the way they thought about their lifestyle and the long-term changes that are required to change their risk behaviours.

This is about my health from now on..... So, that's just the change in me now is suddenly I'm older, this is forever, I need to start being mindful of it all the time, getting more fitness and a better diet. (Patient 6)

I think the concept is really good because this is very much about a lifestyle change. (Patient 8)

You just keep putting a foot forward even if it's only half a foot occasionally. As long as they're not going backwards you keep moving forward and you're right. (Patient 11)

This change was also reported by some patients who did not lose a clinically significant amount of weight.

We both realised the Change Program was a long-term behavioural change and although he hasn't lost weight during the program, he feels he's learnt skills, so that was really good to see. ... But with that one patient in particular who seems to have really taken on board, I guess in particular, changes to physical activity, my feeling is he'll probably maintain those changes for a longer period of time. (GP 44F)

For some patients there was a ripple effect on the lives of others close to them. Some were in charge of preparing their family's food and others influenced friends and family by discussing their own lifestyle change. This level of information would have been lost if interviews with the patient's had not occurred.

You know also the other thing about it is having my wife, I mean she's going to the gym as well now.... she's probably more active than she has been for years, which is really great. You know, and sort of I'd love to get her riding. You know I said, "I want to set us some goals, like just you know the two of us," because I got her a bike and bought her all the gear and everything. (Patient 3)

The other thing, too, [my husband], ... he now joins me, and he's now... actually this has actually impacted on him to get up earlier to go for a walk. So you've actually got another de facto in there as well, so he needs to do something, so in a way he's joined your program. (Patient 13)

This ripple effect also carried through to some of the GPs work. They reported changes in their day-to-day practice with other patients who were not on The Change Program.

I used to be a little bit uncomfortable with it, and now I'm more comfortable saying, "Do you mind hopping on the scale, let's see what you weigh." Doing a waist circumference, which is always a bit awkward when they're big 'cause you can barely reach round the waist. And then opening up the conversation. ... and people are actually relieved and grateful when you do that for them. And I guess before I thought they would be more embarrassed or upset, when they're not, that's what they want. (GP 24B)

I'm going to get my patients in for more regular checkups, just to... rather than sending them off for three months, and not see them in three months, which invariably never happens, but I'm going to start getting them to come in to see the nurse to have a more frequent weigh in, and then I'll touch base with

that consult as well, and go and have a chat to them and see how they're going. (GP 16G)

At the start of the trial GPs were asked specifically about their level of confidence and overwhelmingly it was low.²¹ The GPs were asked again about their confidence managing patients who are obese at the end of the pilot and all but two said they felt more confident.

Do you think that participating in this pilot has changed your confidence around managing patient obesity?

Definitely. It's improved it... it's given me more information, especially to benefit the patient, in terms of the patient education sheets regarding information about the difficulties losing weight, and nutrition and exercise planning. And their worksheets were helpful from... to help structure the ongoing appointments so that we could work through a Program together. (GP 23H)

We are able to describe some of the quantitative data from our sample but must be careful not to draw definite conclusions as there was no control group, no randomisation and we did not have a sufficiently powered sample size as this was a pilot trial. 34.7% of the participants lost 5% or more of their initial body weight at six months. The average weight loss across all 23 recruited patients was 3.2% (standard deviation 3.7, median 1.8%) with a range from -3.2% to 10.5%.

Discussion

REFINEMENT OF PROTOCOL

From the data collected, the research team has suggested the following improvements to the research protocol to plan for a larger scale trial:

1. The recruitment process for patients needs to be refined as it took a long time to recruit the 23 patients. It is suggested that patients are directly alerted to this opportunity in the waiting room (posters and pamphlets), that GPs offer the research opportunity to every patient seen on specific days, and that formal enrolment of the patient onto the trial is undertaken by a research assistant.

GP recruitment is not anticipated to be a problem as the interest of GPs has continued. We have been approached on five occasions after presenting our work, or having it written up in medical media, GPs have requested to use our program materials on their overweight and obese patients, or volunteered to take part in further research. This speaks of the high interest in this topic and the face validity of the program design and materials, as well as the feasibility of recruiting for a larger trial in the future.

2. We had feedback from a small number of patients that would have preferred to do the program with a practice nurse. It is suggested that the patient is asked to choose between appointments with their GP or with their practice nurse. Whoever the patient chooses should see the patient on an ongoing basis during the program. It would be important to also collect data about other appointments with all other health professionals during the trial to assess fragmentation of care.
3. All patients need to be fully aware of what the program offers before they are enrolled. The current patient information sheet meets ethical standards but is densely wordy. An accompanying pamphlet that outlines the processes and requirements of the research in a reader-friendly format should reduce the likelihood of early withdrawals.
4. GP recruitment should be at the practice level with all staff involved in the research. It is important to engage practice managers and receptionists so that they understand the purpose of the program and the research, as well as assisting the GP to overcome the issues with patient recruitment noted earlier. The GPs also need support for invoicing and making appointments. This will increase the sustainability of the intervention.
5. Our original intervention development study found that GPs did not want formal training prior to using The Change Program.¹⁹ However of the GPs involved in the pilot, about half would have liked more formal training on how to apply the program. This could be achieved in a sustainable way by using online tutorials and webinars and incorporated into the GP Continuing Professional Development program. These would need to be developed prior to a larger trial.
6. Online surveys are a good platform for getting participant feedback and assessing outcome measures. We saw a small drop off in the response rate from patients over the six months. Three months would be the suggested minimum time interval between online surveys to avoid participant burn out. The current length of the online surveys seems to be acceptable with all participants completing the surveys.
7. The Physical Activity Scale is a self-report measure which is a limitation if we want accurate monitoring. For a larger trial the use of accelerometers to measure activity randomly in relevant participants would be more accurate.

8. The loss of weight as an end in itself is not necessarily reflective of “good health” as seen in this quote from a patient:

So if I got really sick, like I've got a friend with stomach cancer, she's had all her stomach removed, you know she's thin as thin. People with cancer, thin as thin, they're sick. Or their husbands have left, fantastic, you get really thin (laughs). You know this is really the upside of all that sort of stuff, you know you have a bit of trauma and illness and you'll lose weight like it's going out of style. (Patient 17).

We would suggest the continued use of quality of life measures to ascertain improvement in overall health as well as weight. Additionally fitting with the goals of general practice to be patient-centred, the use of Goal Attainment Scores could be considered as a primary outcome measure.

9. The Binge Eating Score is unlikely to show significant improvement with the use of The Change Program as it identifies patients with disordered eating patterns. It is useful to use the BES initially to identify patients who may be more successfully helped using intensive psychological therapy with a clinical psychologist trained in obesity management.
10. The qualitative data added depth to our research findings and allowed us to assess the impact of The Change Program beyond the individual patient. We suggest that qualitative feedback should be part of a larger trial from random GPs and patients until thematic saturation is achieved. This information will be useful for ongoing assessment of acceptability and feasibility.

REFINEMENT OF PROGRAM MATERIALS

From the feedback given by both patients and GPs we were able to make a number of improvements to the program materials including:

1. Changing the order of the worksheets in the patient workbook and dispersing the behavioural interventions worksheets throughout rather than having one specific section
2. Adding additional information on nutrition to the patient workbook
3. Adding more information on goal setting and motivational interviewing to the GP handbook
4. Changing the tabs on the patient workbook

We also had a copy proof editor review the documents to check consistency of typesetting, grammar and use of language. All the new details were added by our graphic designer who has worked with us since the beginning of the project.

We discussed the heaviness and size of the book with our designer and copy editor. It was agreed that making the book smaller would be impractical as the type set would be too small. The quality of the paper that the book is printed on adds to its weight, but a lower quality of paper would not withstand use over an extended period of time.

The research team also discussed the suggestion from some GPs to have materials given piecemeal over time to the patient. If this were to occur, it would mean the GP would have to store and handle many pieces of paper. We were concerned about papers being lost and a reduction in the “self-management” concept behind the workbook. It was felt that the practicalities of this would make this difficult and the book has stayed as one piece.

Finally the computer template needs to have the capability of complete interaction with the desktop practice software. It is impractical for GPs to copy and paste between different

documents or programs. A standalone template that requires GPs to move between the file and the document is not sustainable over the longer term and an interactive sidebar would need to be developed for further research and clinical use.

TIMEFRAME DEVELOPMENT

For a larger randomised control trial, with the above improvements built in and assuming ethics approval and trial registration, we would suggest the following timeframe is achievable:

1. Recruit GP practices from multiple sites – three months
2. Recruit and train GPs at the sites – six months
3. Recruit patients via GPs with assistance of research officers – six months
4. Ongoing evaluation and data collection – time zero, three months, six to nine months, 12 months, 24 months

HYPOTHESIS FOR EFFECT

After synthesising the qualitative and quantitative data from this pilot trial, we have a number of hypotheses as to why a GP-delivered weight management program could work.

Firstly, the four pillars of general practice fit with providing care to the person who is obese. The aspects that we saw displayed in our pilot include whole-person care where GPs were able to treat acute and chronic conditions and provide preventative healthcare. They were able to do this in the context of the patient's obesity. Whole person care reduces fragmentation and healthcare costs.²²

Secondly, the GPs were able to provide patient centred care. Where they knew the medical and social history of their patients, they were able to tailor the intervention to what suited the situation as well as ceasing measurements when this was unacceptable due to acute patient distress. Patient-centred care is a key indicator for high quality and safe medical practice. The well-documented stigma experienced by patients who are obese in medical and non-medical settings may be a barrier to obesity management. Providing a patient-centred platform for treatment may be one way to improve outcomes.

Finally the relationship between the patient and GP was recognised as a key reason for patients wanting to start The Change Program and for continuing with it. This relationship is likely to be a key factor in the patient's ability to change their lifestyle behaviour. Additionally as the patient-GP relationship is longitudinal it is likely that future interactions could reinforce the changes made in improving overall health.

CONCLUSION

Obesity is an ongoing and increasing health problem for the Australian community. GPs are currently under-utilised in the support and management of patients who are overweight and obese. As GPs already see up to 85% of the population each year, we need to provide them with practical tools to support patients who are overweight or obese. Strong and collaborative patient-GP relationships are likely to be a resource to draw on for long-term lifestyle behaviour change. By using The Change Program and involving GPs in obesity management we can reduce fragmentation of healthcare by looking after patients with a holistic, patient-centred approach which epitomises excellence in general practice.

For more information on the development of The Change Program please refer to:

Elizabeth Ann Sturgiss, Sonia Res, Rebecca Kathage, Kirsty Douglas: *A synthesis of selected clinical guidelines for the management of obesity in general practice*. Australian Family Physician, accepted for publication.

Elizabeth Ann Sturgiss, Kirsty Douglas: *A collaborative process for developing a weight management toolkit for general practitioners in Australia—an intervention development study using the Knowledge To Action framework*. Pilot and Feasibility Studies, 2016;2(20).

Freya Ashman, Elizabeth Sturgiss, Emily Haesler: *Exploring self-efficacy in Australian general practitioners managing patient obesity: a qualitative survey study*. International Journal of Family Medicine, accepted for publication.

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