

Retaining consumer participation in the Fremantle Primary Prevention Study: a general practice team based cardiovascular risk reduction study

Bulsara C¹, Brett T², Seaman K^{1,3}, Arnold-Reed, D²

- 1) *School of Nursing, The University of Notre Dame Australia*
- 2) *General Practice and Primary Health Care Research, School of Medicine, The University of Notre Dame Australia*
- 3) *Brightwater Care Group, Perth, Western Australia*

Abstract—Recruitment and retention of participants to lifestyle modification studies can be challenging within a primary care setting. The management of factors such as travel, busy lifestyles and lack of regular follow up of participants can result in considerable attrition rates over the lifecycle of the project. The aim of the study was to understand from a research participant perspective the perceived barriers and facilitators in retaining community participants in primary health care research. This is a qualitative study with data collected from four focus groups facilitated at the end of each of three community forums focusing on sharing the findings of the Fremantle Primary Prevention Study. Overall twelve focus groups were facilitated with participants that had usual care or who were in the intervention arm of the Fremantle Primary Prevention study. Group size ranged from 6 to 10 participants with the interviewer following a semi structured focus group schedule. Thematic analysis extracted common themes from each focus group around contributing factors to participation. The key message was that relationships built over a longer time period with a GP, practice nurses and other practice staff was an important factor in retention of participants. In addition, ease of travel, convenience and regular check ups with the practice were all significant enticement to remain in a study over the course of the research. Being part of their regular GP practice's involvement in a study was clearly worthwhile as an incentive for participants and offers hope for practice-based research networks undertaking other community-based studies in the future.

Keywords- *Primary health care, consumer participation, CVD risk reduction, General Practice*

II. INTRODUCTION

Consumer interest and participation in health-related research has grown in recent years (1). This research engagement has shown benefits for consumers and communities at a number of

levels (2,3) with ultimate recognition of consumer contribution to health policy development and health services delivery. Positive outcomes include a greater degree of trust and understanding from communities in regard to the purpose of research, greater investment through meaningful involvement in the research process together with improved community satisfaction to the critical question of 'what's in it for me'(4).

These approaches to maintaining consumer interest were endorsed through the Fremantle Primary Prevention Study (FPPS), a risk factor modification study for cardiovascular disease involving 1200 participants over an eighteen month period(5). Men and women aged 40-80 years from three Western Australia general practices were randomized to either an intensive arm involving five study visits to their general practitioner (GP) and practice nurse (PN) or an opportunistic, usual care arm involving two visits to their GP and PN over the study period. Risk factor modification involved a holistic approach including advice from the GP and PN on lifestyle factors such as exercise and diet as well as pharmacological interventions as clinically indicated. The ability to attract and retain interest among study participants was a key strategy to ensure the study's successful completion.

Following the completion of the study and a preliminary analysis of patient data, a series of community forums were held to inform those who had participated in the research about the initial findings and to respond to any community member queries about the research findings. The forum attendees were then invited to participate in facilitated focus groups at the conclusion of each of the forums. The purpose of the focus groups was to ascertain patient perspectives on why they had chosen to participate in the study and what the perceived benefits and barriers were for them. It was intended that this would inform future research direction. This paper presents thematic analysis findings of the qualitative component of the FPPS community forum focus groups.

III. METHODOLOGY

A. Participants

Participants were representative of both the usual care and intervention arms of the FPPS. Four focus groups were held concurrently in each community location. Group sizes ranged between six to ten participants.

B. Methods of data collection and analysis

Each group had a facilitator and scribe assigned and all followed the same interview schedule with areas for discussion outlined as follows:

- The barriers and facilitators to being involved in health research.
- Perceptions of time commitment required to participate.
- Perceptions of feedback provided by the practice nurse or doctor when participating in the research.
- Likelihood of being involved on future research, preferred areas of involvement and why.
- Perceived reasons for lack of participation amongst certain sectors of the community.

All group discussions were digitally recorded and subsequently transcribed by the researcher. Transcripts were analysed using thematic analysis and data managed using the software, QSR NVivo Version 7.0. Ethics approval was from The University of Notre Dame Human Research Ethics Committee.

IV. RESULTS

Participants noted a number of benefits associated with participating in the study including greater awareness and increased motivation in regard to making and maintaining healthy lifestyle changes. Overall, the main benefit across all three sites was having a greater awareness of one's own health status. One participant said that it had 'got me thinking about things I had never thought of before!' and another felt that it made him 'more conscious of what he was doing' in regard to his health. This was motivating for those who highlighted heightened health awareness as a benefit and sparked greater interest in their own health including specific areas such as regular heart health checks and helping them to positively change their lifestyle.

1) Greater awareness and increased motivation amongst participants

Some felt that given their pre-existing risk factor profile, they had 'nothing to lose' in participating and being able to set and achieve targets through the study was regarded as both

beneficial and achievable. Although participants were given the option to decline, many still felt that it would be beneficial to be involved. One participant liked the 'extra attention to my own health' and another said that the benefits of increased activity were beneficial and that she had 'really toned up' through visits to the gym.

Others had longer term reasons for being involved with one saying it had motivated her to maintain good health so that she could enjoy her grandchildren more. One participant termed it as 'an investment' in her own health that was worthwhile given that the check-ups were only three monthly. Deciding to be involved in the study was helped by recent media coverage about leading a healthier lifestyle as a useful approach to disease prevention. Motivation through reading and study involvement was the primary benefit for most participants regardless of whether they were in the intervention group or the opportunistic group. In addition, the exercise component of the program was praised and most found it educational to know their progress was monitored by regular feedback and goal setting.

Educating oneself about maintaining good health was also valued because it allowed a certain amount of autonomy in individualized changes participants wished to make. In this way, some felt that they had a measure of control and input into the pace of change they wished to set. In terms of motivation, self-education and self-management about health were seen as positive outcomes including being aware of one's weaknesses and acting on them to prevent certain negative health behaviours during festive seasons and other events. Although most said that their diet had improved significantly ['my diet has improved 100%'] and that they were 'more conscious of diet', others regarded the changes as more gradual with one describing the small changes made as 'subliminal'. Psychologically, participants felt better about being involved and taking a 'positive step' to improving their health and avoiding the onset of chronic illness. One said that it was the focus on 'prevention' and taking a proactive approach that had interested him in participating. Those who were in the opportunistic, usual care group felt that they would like to have been more involved in the study although they were still able to perceive some of the benefits. For example, one said that the benefit of getting results back from checks was in 'educating oneself' to know what the individual had done well and 'what you had to work on for next time'. Realising the importance of testing was a valuable part of staying involved in the study.

"I was aware that I had to go down and not up [weight] – had to achieve a target and someone keeping an eye on me."

One participant said that the check-ups were 'very helpful with health issues' and that there was a 'more intensive look at your health'; for example, awareness of BMI. There was security amongst participants in knowing that their health was 'being monitored' and that the regular checking of BP and cholesterol was regarded as preventative to worsening health problems. The ability to set targets following regular health checks meant that the participants felt that they had something to work towards. The health checks were regarded by some as

ACKNOWLEDGMENTS

The authors would like to acknowledge the participants of the Fremantle Prevention Study who gave their time and commitment to participating in the study and forum feedback. Also the research team with assisted with the focus group facilitation: Cam Phan, Dana Hince, Robert Moorhead and Wendy Manea- Walley. The study received funding support from: Investigator Initiated Research (IIR) Grant (AUS-Non Drug CVS-06-001) Pfizer, Australia, Western Diagnostic Pathology, Western Australia, The Australian Commonwealth Government Primary Health Care Research Evaluation and Development (PHCRED) Strategy Phase II.

an 'incentive to keep going'. One participant noted that once the doctor had highlighted his 'problem areas' it became an incentive to 'get going' with maintaining a healthier lifestyle. More broadly, some spoke of the altruistic benefits of being involved. In addition, being a part of the community was highlighted as was giving something back to the GP, practice and the community.

2) *The value of regular feedback*

A participant perceived major benefit of this healthy lifestyle program model was the provision of regular feedback regarding individual progress. The importance of being able to ask questions and seek clarification from a practice nurse and / or a general practitioner was highlighted as a benefit. Feedback made participants more aware of their progress and they highlighted the regular feedback component of the study as motivating. Some described the feedback as 'educative' and that it helped with 'better planning for exercise and diet regimen'. Furthermore, participants maintained that it was good to get results back showing that lifestyle changes were successful. Participants also felt very motivated by the ongoing physical activity program and in particular by using a pedometer to determine how much activity they had been participating in. One highlighted the importance of feedback sessions in drawing attention to areas which may need improvement in the future. One said it 'keeps you on track'.

"All depends on blood cholesterol before they tell you anything. So if your cholesterol was up you knew you had to get out and walk more, go to the gym more and watch what you're eating. It keeps you in check".

In addition to this, being able to have regular health checks were perceived as crucial to continued participation in the study. The time spent with the doctor and the practice nurse was also valued by participants.

3) *The role of altruism*

Altruistic reasons of helping someone else in future through research whether it might be a family member or the wider community were highlighted and one participant termed it their 'responsibility to contribute to the quality of life for others in future'. Another said that it was a 'chance to help the community'. In addition, the desire for a healthier lifestyle was a major incentive to take part with participants citing the need to lead a 'healthier lifestyle' as very motivating. The provision of in-depth information about the study was also noted as highly relevant to the decision to participate. Further to this, participants said that they would be less likely to participate in advertised studies through the community or newspaper as there was not enough opportunity to ask questions in regard to the research.

"You see something in the paper, they don't say what's in it for you and you feel like a guinea pig. In this study, you are told at the start that you are going to get checked at 3 month intervals. You value that information up front and all you got to do is turn up."

Some participants believed that they were contributing to society and the future by being involved and that others could

learn from the results of the study. Another said it was good to feel that one was 'giving something back'. One said that he wanted to 'make a contribution to men's health'. Broader altruistic reasons were cited with the future health of the younger generation as uppermost in some participants' minds. *"I wanted to make changes for the younger generation. Help to save money for the community and the country."*

The 'personal approach' in asking persons to be involved in the study was commended by many participants as more of an incentive to be involved. One said that she was made to 'feel important that someone was taking an interest' in her health. Another added that the individualized letter was motivating and another mentioned that being invited to attend the clinic and the forum for feedback was also a benefit.

4) *Convenience factor*

One of the other major facilitators was the ease for participants to become and remain involved in the study. Two mentioned the 'convenience' and another said that it 'made me more aware of things and was not intrusive'. Ease of access with minimal travel to their local practice was also cited by a number of participants in all three groups as a crucial component. Another talked of the minimal time required to be involved in the study. The absence of problems with parking as well as travel was highlighted by a few participants across all three locations.

A participant compared it to his involvement in another dietary research study where he had to travel and then could not get parking at the clinic.

"The advantage is that it is a local study where you go to your usual GP. With a Hospital study you have to get in your car, go to the hospital and there are a lot of factors. You can't even get parked at the hospital! Transport and location are important when you are involved in studies. The easiest is being there for a visit already."

Having the study based in the locale also highlighted the relevance for some participants who felt more involved by 'living locally'. In addition, it was noted that actual clinic appointments were 'only a few times a year' and that appointments occurred when 'I would normally go anyway'. Further participants said that it was 'not too hard' and 'not too demanding'. One described another study that he had been involved in which required him to record information 'every fifteen minutes' and he found this too intrusive and demanding of his time. Several participants spoke of the age group that they were in as a possible factor in maintaining numbers in the study. A number of participants had already retired and this 'freed up time' for them to attend any extra appointments and feedback sessions. Also, in allowing time to include more regular exercise and lifestyle improvements, it indicated that time commitment may be more of an issue for younger age groups.

5) *Barriers to being involved*

Although most participants had seen positive benefits from involvement some with smaller marked improvements in results were less enthusiastic. One noted that he had the same

measurements before and after despite being part of the 'intensive group' and that he had expected more significant changes. Another said that their cholesterol had not changed as expected and that this had caused, '*frustration that the goal had not been met even though I had tried...*' Unexpected and 'less than positive' results were more likely to deter participants. One participant mentioned '*...a little voice in your head asks if you are doing the right thing*'. The importance of having regular check-ups and feedback sessions helped to allay fears and doubts for most. One participant said that the only barrier for him was the necessity for blood tests and 'needles'. Another mentioned the downside of having to queue to have blood tests performed at the clinic as part of the study. Couples participating in the study also found it a drawback to attend a different practice from their partner with increased waiting times between two locations. In addition, a few noted they were not as 'inspired' as they thought they would be by participating. A few in the opportunistic group would have preferred to have been part of the intensive group.

6) Relationship with GP, PN and practice staff

Many mentioned their relationship with the GP as a factor in becoming involved in the study. Some had long-term relationships with the GP, PN and practice staff and felt comfortable and trusting in agreeing to participate. One noted that the doctor was 'very positive' about the study and this had encouraged him to be involved. The GP having 'the right attitude' was noted by a number of participants in encouraging them to participate as well as taking time to explain the study to participants and allowing them to ask questions as an incentive to join. One said that they were made to 'feel important and that someone was taking an interest' in her health.

"It is about the personal approach you know. [My GP] asked if we wanted to be on the program and explained it. It wasn't invasive and you just come like you always come."

Clearly, the enthusiasm of the GP, PN and practice staff made involvement in the study more appealing to a number of participants. Participants in all focus group locations had similar positive relationships with the practice and reported that 'practice staff made it easy' and 'the staff are very good.' as endorsements of their support. The individual approach from the practice was highlighted as crucial to the decision to be involved for a number of participants. Another recognized this by saying that had it not been conducted in the personalised way, '*...there would not have been 400 [persons] participating*'.

IV. DISCUSSION

Cardiovascular disease continues to pose the greatest mortality risk to all patients worldwide with the risks increasing progressively with advancing years. The FPPS involved a cohort of 40-80 year old men and women with no prior history of cardiovascular disease and sought to modify potential risk factors for the condition. The study successfully recruited

1200 participants to the study and retained the interest of 93% over an eighteen month period until study completion. Enthusiasm for patient involvement in the research process was unexpectedly high throughout with many requesting its continuation beyond completion date. Patient reflections on their experience of primary care research was canvassed and analysed.

The primary care setting is ideally situated to offer the vast majority of patients positive health messages on a regular basis(6). Up to 91% of problems presenting to general practitioners are managed at the primary care level(7) while about 86% of patients consult their GP at least once every year(8). Despite this intense patient contact, research evidence on the generally successful outcomes from these primary care encounters has received much less research acknowledgement compared with that emanating from secondary and tertiary level care. This lack of a substantial evidence-based research output has contributed to the lack of investment both in primary care practice infrastructure and in capacity building to facilitate the production of practice-based clinical research. Evidence from our community forums and focus groups suggest strong support from patients and communities for this type of real-time evidence gathering at the primary care level. Clearly, within this age group, the benefits of being involved in a community-based, long-term health study outweighed any disadvantages. The convenience of access to primary care practices came across very strongly from all three practice locations. High interest in supporting the research process for personal, community and altruistic motives was also common throughout. A key factor appeared to be the high level of trust between participants in the study, the general practitioner and practice nurse. At all three practices, the GP and practice nurse were seen as key members of the research team and this extra dimension of their work added considerably to the success of the research process. This is an important element to consider when conducting a successful study, as studies have shown that a common barrier is when priority is 'given to clinical and administrative matters over the research participant'(9). Also, one study has highlighted that retention rate is affected when providers 'offered little discussion' about the study(10). Due to the dedication and commitment of the three practices involved these common issues were not perceived as a barrier. Increased patient awareness of what exactly primary prevention of cardiovascular disease actually meant to their daily lives added an extra motivation to get engaged and stay involved in the study. Undertaking regular health checks began to take on new significance as patient appreciation of the overall research strategy became more established. The ease of access to their community-based practice enabled greater feedback and advice for patients and helped them 'keep on track' to achieve target goals. Many participants spoke of the personalized approach that made them feel wanted, that their primary care team had a genuine interest in their health and that they were not being used as simply a number on a database. The increased awareness of the significance of family history especially for diabetes, heart and

kidney disease was noteworthy for future approaches in this area.

A key message from the focus groups was the successful relationships that patients had built up with various members of the primary care team, not just the GP and PN but also reception staff and allied health including dietician. The ability of general practice to offer such a holistic approach in their own environment provided greater poignancy and appeared to be an added incentive for participants to remain involved in the study. For some, prior experience with hospital-based research studies tended to have had a negative or neutral impact. Being part of their own practice's involvement in a study with special meaning for them was clearly a bonus emphasizing the potential of general practice-based research networks to undertake other community-based studies in the future.

REFERENCES

[1] Minkler M, Wallerstein N. community-based participatory research for health: from process to outcomes. 2nd edition. Jossey-Bass, CA. 2008.

[2] Baggott R, Forster R. Health consumer and patients' organisations in Europe: towards a comparative analysis. *Health Expectations*. 2008;11(1):85-94.

[3] Wilson A. Consumer participation: ensuring suicide prevention research counts for end users. *International Journal of Nursing Practice*. 2010;16(1):7-13.

[4] Christopher S, Watts V, McCormick A, Young S. Building and maintaining trust in a community-based participatory research partnership. *American Journal of Public Health*. 2008;98(8):1398-406.

[5] Brett T, Arnold-Reed D, Phan C, Cadden F, Walker W, Manea-Walley W, et al. The Fremantle Primary Prevention Study: a multicentre randomised trial of absolute cardiovascular risk reduction. *British Journal of General Practice*. 2012;62(594):e22-e8.

[6] Harris M. The role of primary health care in preventing the onset of chronic disease, with particular focus on the lifestyle risk factors of obesity, tobacco, and alcohol. Commissioned Paper for National Preventative Health Taskforce; 2008.

[7] Britt H, Miller G, Charles J, Henderson J, Bayram C, Valenti L, et al. General Practice activity in Australia 2000-01 to 2009-2010: 10 year data tables. In: AIHW, editor. *General Practice Series*. Canberra 2010.

[8] Pegram R, Daniel J, Humphries J, Kalucy L, Maclsaas P, Mott K, et al. *General Practice in Australia 2004*. In: Ageing DoHa, editor. Canberra 2004.

[9] Mason V, Shaw A, Wiles N, Mulligan J, Peters T, Sharp D, et al. GPs' experience of primary mental health research: a qualitative study of the barriers to recruitment. *Family Practice*. 2007;24:518-25.

[10] Locatelli S, Sohn M-W, Spring B, Hadi S, Weaver F. Participant Retention in Veterans Health Administration's MOVE! Weight Management Program, 2012. *Prev Chronic Dis*. 2010;9(120056).



Associate Professor Caroline Bulsara is research coordinator within the School of Nursing and Midwifery at the University Of Notre Dame (Fremantle). Previously, Caroline has worked in a number of leadership roles both within the universities and externally in a large not for profit organisation to build research capacity. She has a strong interest in qualitative and community and consumer participatory research including expertise in working with disadvantaged and marginalised populations.