

BMJ Open Evaluating a custom-designed aid to improve communication of genetic results in families with hypertrophic cardiomyopathy: study protocol for a randomised controlled trial

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To cite: Burns C, Yeates L, Semsarian C, *et al*. Evaluating a custom-designed aid to improve communication of genetic results in families with hypertrophic cardiomyopathy: study protocol for a randomised controlled trial. *BMJ Open* 2019;**9**:e026627. doi:10.1136/bmjopen-2018-026627

► Prepublication history and additional material for this paper are available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2018-026627>).

Received 12 September 2018
Revised 6 December 2018
Accepted 10 December 2018



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ABSTRACT

Introduction Genetic testing for hypertrophic cardiomyopathy (HCM) in the era of genomics brings unique challenges for genetic counselling. The number of genes routinely included in an HCM gene panel has increased markedly, many with minimal if any robust evidence of gene–disease association. Subsequently, there is a greater chance of uncertain genetic findings. The responsibility of communicating this information with at-risk relatives lies with the index case (proband). We have developed a communication aid to assist with the delivery of genetic results to the proband. We have previously shown the aid is feasible and acceptable and have now developed a study protocol for a randomised controlled trial of a genetic counsellor-led intervention incorporating the communication aid.

Methods and analysis This is a prospective randomised controlled trial. We will investigate the impact of a genetic counsellor-led intervention to return proband genetic results using a custom-designed communication aid. We aim to improve knowledge and empowerment. The primary outcome of this trial is the ability and confidence of the proband to communicate genetic results to at-risk relatives. Secondary outcomes will assess genetic knowledge, satisfaction with services, outcomes from genetic counselling and psychological adaptation to genetic information.

Ethics and dissemination This study has been approved by and is in strict accordance with the Sydney Local Health District Ethics Review Committee (X16-0030; 22/01/2016; version 1). Results from this trial will be prepared as a manuscript and submitted to peer-reviewed journals for publication as well as submission for presentation at national and international meetings.

Trial registration number ACTRN12617000706370.

INTRODUCTION

Background and rationale

Genetic testing in the era of genomics brings unique challenges for the genetic counselling of families. Hypertrophic cardiomyopathy (HCM) is a clinically heterogeneous inherited heart disease characterised by

Strengths and limitations of this study

- This study will assess the effectiveness of a communication aid to improve the ability and confidence of patients with hypertrophic cardiomyopathy (HCM) to communicate genetic test results with their at-risk relatives.
- The results of this trial will inform genetic counselling practice for HCM genetic testing, as well as be broadly applicable for other inherited heart diseases.
- Limitations include the generalisability of our findings, which are true for a specialised multidisciplinary clinic where the intervention was performed but may not be representative of the broader HCM population undergoing genetic testing.
- As genomic technologies continue to evolve, uncertainty and complexity of genetic findings will likely increase over time.

unexplained left ventricular hypertrophy in the absence of a loading condition such as hypertension.¹ With a prevalence of 1 in 200–500, it is one of the most common inherited heart diseases and clinical manifestations can range from asymptomatic through to heart failure or sudden cardiac death.² In the setting of HCM, genetic testing of the index case (proband) can provide invaluable information by allowing at-risk relatives the opportunity to undergo cascade genetic testing to look for the presence or absence of the family-specific variants.³ The first step is often the most challenging, requiring identification of a variant for which there is sufficient evidence of causation.

Genetic counselling is a critical aspect of the process for genetic testing and for understanding inheritance risks, characterisation of the family history, and emotional support.⁴ Within a clinical setting, pretest and post-test genetic counselling should include discussion

of inheritance risks and clinical screening guidelines for at-risk relatives.⁵ This allows asymptomatic at-risk relatives to make proactive, informed decisions regarding their risk, including family planning decisions.

How a patient understands and communicates this genetic information to their at-risk relatives is critical to ensuring patients' get the most value out of genetic testing. This task of communication relies on the proband within the family. Current Australian practice and privacy laws dictate that in most cases the healthcare provider does not make contact with relatives to disclose risk information. Therefore, it follows that in order to communicate genetic results or risk information, the proband must have adequate understanding of the information they have received from their healthcare provider. Several studies indicate this may be problematic, and some individuals may not retain or understand the information presented to them.⁶

Existing knowledge

Currently, literature estimates between 20% and 40% of relatives remain unaware of relevant genetic information and do not act on information even when they have reportedly been informed of their risk.⁷⁻⁹ Many factors have been identified that influence family communication about genetic risk, including complicated family dynamics, guilt, anxiety and gender; however, these factors are difficult to target as areas for improvement within the context of one or two genetic counselling sessions.^{7 8 10 11} There are stages within the genetic counselling process, where communication of genetic results and uptake of appropriate screening may be influenced.

Our group and others have shown some of the barriers that can negatively impact on family communication. In a qualitative study of patients with HCM undergoing comprehensive genetic testing, many patients reported uncertain results to be conveyed less among families.¹² Furthermore, these results are often misunderstood. For example, among this cohort, probands with uncertain results perceived these results as falsely reassuring or conversely suggests their disease is 'worse' or 'different'. This led to a misunderstanding that their result was not heritable, and therefore, communication with relatives did not occur.¹² Supporting these findings, the general genetics literature highlights that risk perception and understanding of results, though varied, can be poor, inaccurate and incomplete.^{13 14}

There is evidence for the effectiveness of a genetic counsellor in addressing some of the communication and knowledge barriers.¹⁵⁻¹⁷ One key area for intervention is during the post-test genetic counselling session. Genetic and risk information can be difficult to understand and explain clearly and as a consequence, the patient may not gain sufficient knowledge and lack confidence to convey these key messages to at-risk relatives.¹² Furthermore, it has been shown that patients deliberate on the appropriate time to communicate genetic information and make their own decisions regarding which relatives

they will inform, regardless of the recommendation of professionals.^{7 18 19} Few resources exist that aim to facilitate effective communication to at-risk relatives. We therefore hypothesise that improving knowledge of an HCM genetic diagnosis will have a positive impact on communication to at-risk relatives, as well as genetic knowledge, satisfaction with services, outcomes from genetic counselling and psychological adaptation to genetic information.

Utility of a communication aid

When asked about family communication, most patients report families should communicate risk among

Table 1 Trial registration data

Primary registry and trial identifying number	Australian New Zealand Clinical Trials Registry: ACTRN12617000706370
Date of registration in primary registry	17/05/2017
Secondary identifying numbers	NA
Source(s) of monetary or material support	National Heart Foundation of Australia
Primary sponsor	The University of Sydney
Secondary sponsor	NA
Contact for public queries	Dr Jodie Ingles j.ingles@centenary.org.au
Contact for scientific queries	Dr Jodie Ingles j.ingles@centenary.org.au
Public title	Use of an aid to improve communication of genetic risk information to families with hypertrophic cardiomyopathy (HCM)
Scientific title	Use of a custom designed aid to improve communication of genetic results in families with HCM
Countries of recruitment	Australia
Health condition (s) or problem (s) studied	HCM
Intervention	Use of a custom designed aid to communicate HCM genetic test results
Key inclusion and exclusion criteria	HCM probands with a genetic result ready for return. Participants must be aged 18 years or older. Sufficient written English skills as nominated by the participant.
Study type	Prospective randomised controlled trial
Date of first enrolment	25 November 2016
Target sample size	45
Recruitment status	Recruiting
Primary outcome (s)	Ability and confidence of the proband to communicate genetic results to at-risk relatives.
Key secondary outcomes	Secondary outcomes will assess genetic knowledge, satisfaction with services, outcomes from genetic counselling and psychological adaptation to genetic information.

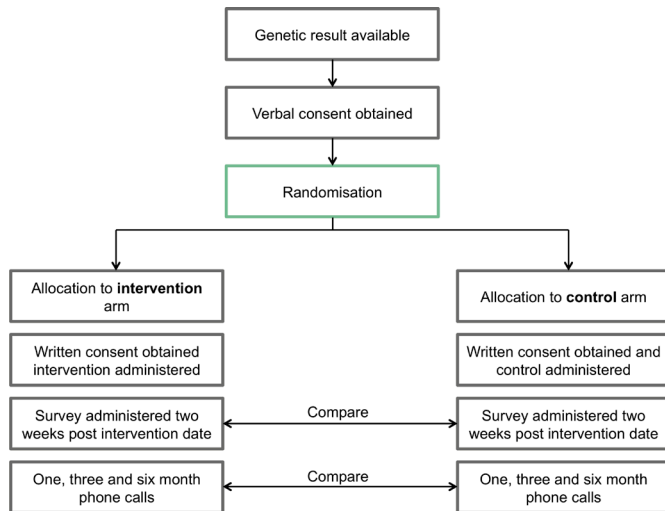


Figure 1 Flow chart of overall study design.

themselves with varying levels of support from their healthcare providers.^{14 17 20} In addition, there is evidence for the effectiveness of genetic counselling to assist with this process.^{15 16 20} Hodgson *et al*²¹ published a randomised controlled trial assessing the impact of a genetic counselling phone intervention on communication of genetic information within families. They found no significant difference between the intervention and control group when measuring contact with genetic services, though in subanalyses of the high-risk children group, the primary outcome was significantly improved. Importantly, the primary outcome measure was contact with a genetic service, which can be difficult to ascertain and may not be the most accurate measure of effectiveness or a direct reflection of communication efforts.

Resources such as decision and communication aids, or family letters, may provide additional support to this process, though more data are needed regarding efficacy.^{15 19 21 22} Decision or communication aids are tools specifically designed to support patients with decision making and unmet information needs. There is evidence for the effectiveness of an aid with regard to improved knowledge and accuracy of risk perceptions.^{23–25} Furthermore, most health information is provided in a written format, which may not be the most effective health communication method. Communication and decision aids provide a format to include visual elements that may improve comprehension, recall and comfort with the information, particularly when health literacy may be an issue.

Need for a trial

Overall, the literature highlights that probands require additional support to understand and communicate genetic results. The rationale for this study is the critical gap in supporting patients' comprehension and consequent communication of genetic risk to at-risk relatives. Though genetic counsellors are specifically trained in delivering genetic information, information

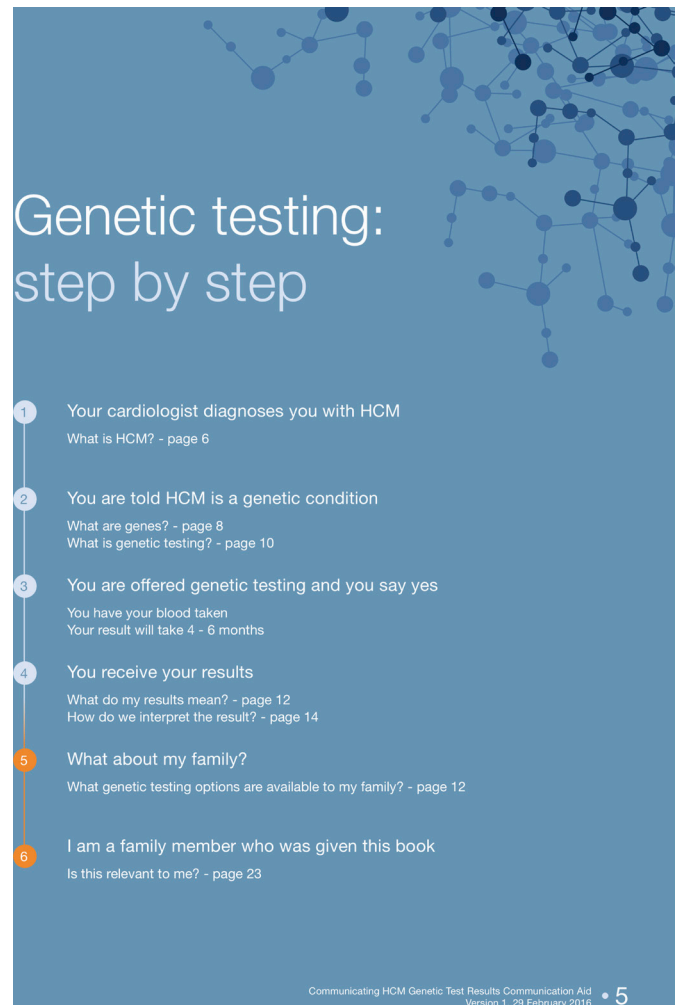


Figure 2 Example page from communication aid: genetic testing step by step. HCM, hypertrophic cardiomyopathy.

needs of patients are not always met and communication among at-risk relatives can be suboptimal. As genetic test results become increasingly complex, an evidence-based approach to supporting patients with genetic knowledge and risk communication should be explored.

Study aims and outcomes

The aim of this randomised controlled trial is to determine if a genetic counsellor-led intervention using a communication aid for the delivery of HCM genetic test results improves the ability and confidence of the proband to communicate genetic results to at-risk relatives compared with current clinical practice.

1. The primary outcome is the ability and confidence of the proband to communicate genetic results to at-risk relatives, measured at 2 weeks postintervention.
2. Secondary outcomes will assess genetic knowledge, satisfaction with services, patient reported outcomes of genetic counselling and psychological adaptation to genetic information, measured at 2 weeks postintervention.
3. As a longer term outcome, we will systematically assess and document family communication as reported

What is my genetic result?

Test Result	The Impact for You	The Impact for Your Family
Pathogenic (page 18)	This result is considered to be the definite cause of your disease.	We can look for the same variant in family members (cascade genetic testing).
Likely (probably) pathogenic (page 18)	This result is considered to be important and with the available evidence is thought to be the cause of HCM.	We can look for the same variant in family members (cascade genetic testing).
Variant of unknown significance (VUS) (page 20)	Currently we do not know if this variant is the cause of HCM or not. More evidence is needed.	Continue with current clinical screening guidelines, no cascade genetic testing options available at this time.
Benign or likely benign (page 16)	This variant is not the cause of HCM.	Continue with current clinical screening guidelines, no cascade genetic testing options available at this time.
No variant identified (indeterminate) (page 15)	No HCM variants have been identified.	Continue with current clinical screening guidelines, no cascade genetic testing options available at this time.

How certain are we that a variant is the cause of HCM?

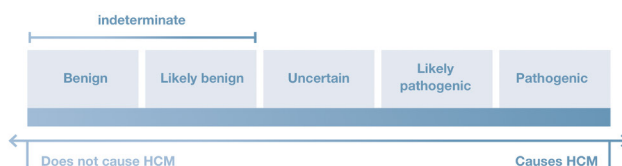


Figure 3 Example page from communication aid: what is my genetic result?

by the proband measured by phone calls at 1, 3 and 6 monthly intervals. The researcher conducting these phone calls will not be blinded to the treatment arm of the participant. During these phone calls, a series of questions regarding family communication and uptake of family screening will be asked of the proband. These phone calls will be conducted and analysed after collection of the primary and secondary outcomes data. This is to prevent interference with results because the phone calls themselves may serve as a family communication intervention. A phone script to be used as a guide for these phone calls is available in the online supplementary material.

METHODS AND ANALYSIS

Trial design

This is a prospective randomised controlled trial. The protocol is reported in accordance with the Standard Protocol Items: Recommendations for Interventional Trials statement, which provides recommendations for a minimum set of scientific, ethical and administrative elements that should be addressed within a clinical trial protocol.²⁶ All items from the WHO Trial Registration Data Set are listed in [table 1](#). Consecutive patients with HCM will be invited to participate when they are notified on the phone that their genetic result is ready to be returned. Once written consent is obtained, they will be randomised to receive their genetic result via the intervention or control arm of the study ([figure 1](#)).

Study setting

This trial will be carried out within a specialised multi-disciplinary HCM clinic. This incorporates the expertise of specialist cardiologists and cardiac genetic

counsellors.²⁷ Patients with HCM attending these clinics at Royal Prince Alfred Hospital will be invited to attend.

Eligibility criteria

HCM probands with a genetic result ready for return are eligible. HCM probands are defined as the first person in the family to undergo genetic testing for HCM. Probands include those with and without a family history of disease provided genetic testing has been ordered. Participants must be aged 18 years or older, with sufficient written English skills as nominated by the participant. Genetic testing is performed as part of a research study, or commercial laboratory as previously published.^{28 29} All identified variants are classified in the same manner, as per current clinical standards and guidelines.³⁰ Recruitment commenced in November 2017 and is expected to end in November 2018. Participants will be invited to participate in the study during their routine preclinic phone call conducted as normal clinical process. Informed consent will be obtained by the cardiac genetic counsellor present at the participants clinic consultation (online supplementary material).

Randomisation

A randomised list was prepared using the Excel (Microsoft Office) 'Random' function, and study participants who consent to the study are allocated the next number on the random list. This number is linked to either control or intervention. A researcher not involved in the study performs the randomisation.

Sample size and power calculations

Prior to commencement of the study, power calculations were performed using the results from our published feasibility study.³¹ The primary outcome of this trial is the

My family summary

Sharing this booklet with family members is encouraged.

If you're a family member reading this booklet, hopefully you will find some details below that apply directly to you.

All first-degree relatives of someone with HCM are recommended to have clinical screening to check for signs of HCM. This includes children, brothers/sisters and parents.

Clinical screening involves: echocardiogram (ultrasound of the heart) electrocardiogram (or ECG, an electrical trace of the heart rhythm), and physical examination with a cardiologist.

First name	Relation	Age	Clinical Screening	Genetic testing possibilities

Clinical screening guidelines for family members

Family member's age	How often you should see a cardiologist
0 - 5 years	Optional
6 - 10 years	Every 3 - 5 years
11 - 20 years	Every 12 - 18 months
21 - 30 years	Every 2 - 3 years
31 or more years	Every 3 - 5 years

This only applies to first-degree relatives (i.e. parents, brother/sister and children) of someone with HCM. If anyone in the family is having any symptoms suggesting a heart problem, they should see a cardiologist.

Figure 4 Example page from communication aid: family-screening guidelines.

ability and confidence of the proband to communicate genetic results to at-risk relatives. Data from the feasibility study indicated 75% of participants communicated genetic results to at-risk relatives. Assuming the control group communicates in 50% of cases, at a significance level of 5% and 80% statistical power, a sample size of n=21 is required per group.

Development of the custom communication aid

We have developed a communication aid to assist with the delivery of genetic results to the proband and support family communication. A pilot study demonstrating feasibility and acceptability of this aid has been previously reported.³¹ In brief, development of the aid involved review of the literature alongside multidisciplinary meetings. Development was a multistep process and on the basis of meeting outcomes, literature review and empirical evidence from the multidisciplinary team. The aid addresses:

1. Genetic test basic background information.
2. Possible outcomes of genetic testing.
3. Overview of the process involved in classification of a genetic variant.
4. Implications for at-risk relatives including family screening recommendations.

Control arm

Those within the control arm of the study will receive their result via normal clinical practice. There are currently no evidence-based guidelines for return of comprehensive genetic test results within the multidisciplinary clinic setting. Normal clinical practice typically involves return of a genetic result either by the cardiologist or genetic counsellor. Return of the result is usually performed following clinical cardiology review, which is often the

primary purpose of the consult. In the majority of cases, a genetic counsellor is present.

Intervention arm

Those randomised to the intervention arm will be allocated a separate appointment time after clinical review with their cardiologist, where they will see the cardiac genetic counsellor who will return their genetic result using the communication aid.

The communication aid covers the process of genetic testing and risk from diagnosis of HCM through to the implications of a genetic result for at-risk relatives (figure 2). There is a section in the aid under 'Results', which goes through the meaning of each category of genetic result. These include an indeterminate result (no variant identified), a variant of uncertain significance and a likely pathogenic/pathogenic result (figure 3). The genetic counsellor returning the genetic result will mark the appropriate category of result, which applies to the patient in front of them. The genetic counsellor will return the genetic result, and then go through the communication aid, referencing the individual result and specific recommendations for the rest of the family. There will be an opportunity to ask questions, and the genetic counsellor will write the specific recommendations for each family member in the box provided at the end of the communication aid (figure 4).

Patient and public involvement

Development of this research question and outcome measures were informed by clinical experience of the authors in a specialised clinic setting, as well as published research identifying gaps in communication with relatives. Specifically, there are known challenges associated with understanding and subsequent communication of

genetic information to relatives. We have shown poor understanding, recall and communication of genetic results among HCM probands.^{7 12} Prior to implementation and development of this trial, a pilot study involving patients was conducted, incorporating patient preference and needs allowing development of both the communication aid and the study protocol.³¹ Results will be disseminated to patients in the form of a research participant newsletter on completion of the study. In addition, those randomised to the control arm will receive a copy of the communication aid. Patients provided written consent to participate in the study, with an understanding of the requirements of the study. These were not considered by the patients or study team to be burdensome for the patients participating in the study.

DATA COLLECTION AND OUTCOMES

Both the primary and secondary outcomes will be measured at a single time point (2 weeks postintervention) using a survey comprised of a number of previously published and validated scales. A number of demographic questions will also be asked within the survey. The survey will be available online via qualtrics (<https://www.qualtrics.com/>) with a direct link sent to participants. For those who prefer a hard copy, it will be posted with a return envelope. The survey will be sent 2 weeks after return of genetic results. Evidence regarding the most appropriate time between genetic result disclosure and family communication is lacking. However, given the risk of arrhythmia and sudden death within the inherited heart disease context, 2 weeks postresult disclosure was considered by the study team to be an appropriate time point to send the survey.²⁵ Return of the survey is followed up on a fortnightly basis.

Primary outcome

The primary outcome of this trial is the ability and confidence of the proband to communicate genetic results to at-risk relatives. This will be measured at a single time point, administered 2 weeks after return of genetic results. Ability and confidence will be assessed by two measures and then combined into a binary outcome. The certainty subscale of the Psychological Adaptation to Genetic Information (PAGIS) scale will measure confidence with genetic knowledge.³² This subscale measures the patients' perception and confidence in their genetic knowledge, and the items from this subscale are listed in [box 1](#). Subsequent ability to pass this information on will be measured by the number of at-risk relatives informed of genetic results by the proband. We will average the scores from both measures to determine a final score. The calculations used to determine this cut-off are illustrated in [box 2](#).

In summary, we will calculate the total PAGIS certainty subscale score (denominator of 36). This will be added to the total number of relatives informed over the total number of relatives at risk. This number will

Box 1 Certainty subscale of the PAGIS scale

1. I understand how I came to have hypertrophic cardiomyopathy.
2. I understand the health risks my relatives face because of hypertrophic cardiomyopathy.
3. I feel certain that I understand the meaning of having hypertrophic cardiomyopathy.
4. I understand the chances I have of passing hypertrophic cardiomyopathy along to my children.
5. I feel that I can explain to other people what having hypertrophic cardiomyopathy means.
6. I feel confused because I have been given different explanations of what having hypertrophic cardiomyopathy means.

PAGIS, Psychological Adaptation to Genetic Information Scale.

then be converted to a percentage. The final score will be converted to a binary outcome of fair versus poor ability and confidence to communicate genetic results to at-risk relatives. A cut-off of $\geq 75\%$ will be used to indicate fair communication, based on data indicating 20%–40% of relatives are not informed of their genetic risk. This outcome has been specifically designed for this study.

Factors that influence communication of genetic results to at-risk relatives are multidimensional. For this reason, we chose this combination approach to more broadly reflect the communication process. Many studies rely on single and linear measures of communication such as contact by relatives with genetics departments or self-reported communication with at-risk relatives only. To overcome this, we aimed to incorporate a multidimensional approach that included the probands confidence regarding their knowledge of genetics alongside the

Box 2 Primary outcome measure converted to a primary outcome

Measures incorporated

1. Certainty sub scale from PAGIS (measuring confidence).
2. Adult first-degree relatives informed of genetic risk (measuring ability).

Calculation examples

Example 1:

Certainty score from PAGIS subscale = $18/36 = 0.5$.
 Relatives informed of risk = $3/6 = 0.5$
 $= (0.5 + 0.5) / 2 = 0.5$
 $= 50\%$.

Therefore, this participant falls into the 'poor communication' category of the primary outcome

Example 2:

Certainty score from PAGIS subscale = $30/36 = 0.83$.
 Relatives informed of risk = $7/8 = 0.88$
 $(0.88 + 0.83) / 2 = 0.86$
 $= 86\%$.

Therefore, this participant falls into the 'fair communication' category of this primary outcome.

PAGIS, Psychological Adaptation to Genetic Information Scale.

action linked to this knowledge, being the communication to relatives. This will aim to determine consistency between the probands confidence with genetic information against their self-reported percentage of immediate family members informed.

The certainty subscale of the PAGIS will be used to measure confidence with genetic knowledge as described above.³² Guided by grounded theory in patient perspectives of genetic counselling and the Roy Adaptation to Genetic Information Model, the 26-item PAGIS allows for evaluation of the efficacy of genetic counselling.^{32 33} The scale aims to incorporate the multidimensional adaptation to genetic information and comprises of five domains that include: (A) non-intrusiveness, (B) support, (C) self-worth, (D) certainty and (E) self-efficacy.³² Evidence for the utility of this scale has been published and illustrates its potential use for assessing genetic counselling interventions.³²

Secondary outcomes

The survey comprises three additional scales to assess primary and secondary outcomes, a number of questions regarding communication with relatives, as well as a number of demographic questions.

Genetic knowledge will be assessed using an amended version of the Breast Cancer Genetic Counseling Knowledge Questionnaire.^{33 34} This scale was originally developed to assess knowledge of information typically included in genetic counselling for breast cancer. The original scale was a 27-item questionnaire including statements regarding genetics such as ‘50% (half) of your genetic information was passed down from your mother’, and participants were asked if the statement was true or false. Items in the original scale were empirically derived from detailed content analysis of breast cancer genetic counselling sessions. The original scale demonstrated a high content validity with Cronbach’s $\alpha=0.92$, with demonstrated ability to discriminate between patients before and after genetic counselling sessions.³⁴ We have amended questions to reflect the HCM context, and 10 items were included.

Satisfaction with services received will be assessed using the widely used Satisfaction with Genetic Counselling Scale.³⁵ The original questionnaire was designed to assess three dimensions of patient satisfaction: instrumental, affective and procedural.^{33 35} This survey will use an amended version of the 12-item short form of the survey.

The Genetic Counselling Outcome Scale will be used to assess patient-reported outcomes of genetic counselling.³⁶ The questionnaire was designed to be used pre-genetic and postgenetic counselling, though we have used it in the postcounselling setting. The authors of this scale used the construct of empowerment to summarise the patient-derived benefits from genetic counselling.

Data management

All data from the survey will be entered into Microsoft Excel. Patient identifiers will be removed with study codes

allocated. The primary researcher will be blinded to treatment arm of the patient for analysis of the primary and secondary outcome data. A second senior researcher and supervisor will oversee data storage and analysis. Data will be stored in accordance with the Sydney Local Health District Ethics Review Committee and Centenary Institute.

Data analysis plan

Data will be analysed using Prism (V.7.0) and SPSS (V.23.0). We will compare the primary outcome as a binary measure between the intervention and control group. We will use chi-square analyses using $p<0.05$ for statistical significance. For assessment of secondary outcomes, we will be guided by published scoring systems for the validated scales to score genetics knowledge, satisfaction with services and genetic counselling outcomes. Mean scores for each scale will be compared between the intervention and control group, and comparisons between the control and intervention group will be analysed using unpaired t-tests for continuous data and χ^2 analysis for categorical data. Subgroup analysis will also be performed; specifically, we will compare outcomes in the study groups stratified by the genetic result (ie, causative, uncertain or indeterminate results) and compare familial and non-familial HCM probands, which has been previously shown to influence family communication practices.³⁷

As a longer term outcome, we will systematically assess and document family communication as reported by the proband measured by phone calls at 1, 3 and 6 monthly intervals. These phone calls will also measure uptake of family screening as reported by the proband. This will be assessed separately to the primary and secondary outcomes. We will compare outcomes between the study groups stratified by the genetic result (ie, causative, uncertain or indeterminate results). In addition, we will compare outcomes between study groups stratified by those with and without a family history of HCM.

ETHICS AND DISSEMINATION

Dissemination

Results from this trial will be prepared as a manuscript and submitted to peer-reviewed journals for publication. In addition, it will form part of the first authors’ PhD thesis. Results from the study will be submitted to international and national scientific sessions with the aim of being presented. We will make a copy of the aid available to a wider genetic audience for use in their clinical practice, and study data will be available from the authors. This will include development of an electronic form of the aid.

Acknowledgements We would like to thank Yana Smagarinsky for her assistance with developing the communication aid and Katharine Morgan for graphic design of the communication aid.

Contributors All authors contributed to the manuscript, specifically: substantial contributions to the conception or design of the work; the acquisition, analysis or interpretation of data for the work; drafting the work or revising it critically for important intellectual content; final approval of the version to be published; and agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Funding CB is the recipient of an Australia Postgraduate Award. CS is the recipient of a National Health and Medical Research Council Practitioner Fellowship (#1059156). JI is the recipient of a National Heart Foundation of Australia Future Leader Fellowship (#100833).

Competing interests None declared.

Patient consent Obtained.

Ethics approval All aspects of the study will be performed according to institutional human research ethics committee approval. This study has been approved by and is in strict accordance with the Sydney Local Health District Ethics Review Committee (X16-0030).

Provenance and peer review Not commissioned; externally peer reviewed.

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