



Women's Experience of Later Termination of Pregnancy in Scotland (WELTOP): an exploratory research study

Research Protocol (version 2)

MRC/CSO Social & Public Health Sciences Unit

Commissioned and funded by the Scottish Government

Summary

The legal limit for abortion in Great Britain is 24 weeks (except to prevent grave permanent injury to the physical or mental health of the pregnant woman, to save the life of the pregnant woman or for severe foetal abnormality). However, the provision of later second trimester termination of pregnancy varies between NHS boards in Scotland and most do not provide abortion after 18 weeks gestation (unless for the above exception). Currently, other women requesting termination after 18 weeks have to travel to England for the procedure. Research studies suggest there are numerous reasons a woman might request a termination after 18 weeks. These include delays in accessing and obtaining terminations, delays in realising or recognising pregnancy, denial, ambivalence about having an abortion, concerns about what is involved, relationships with partners (and parents), and changes in life circumstances. However, none of the studies have focused on the experiences of women in Scotland or of women who request, but do not go ahead with an abortion. This 12 month study, commissioned and funded by the Scottish Government, will explore the experiences of women in Scotland presenting later for termination of pregnancy. Women presenting at 16 weeks gestation or above at termination of pregnancy clinics in five NHS boards (Greater Glasgow & Clyde, Lothian, Ayrshire & Arran, Grampian and Highland) will be invited to take part in an in depth interview. We aim to recruit a minimum of 30 women (15 who proceed and 15 who do not proceed with a termination). Participants will be asked about their pregnancy and abortion experiences and reasons for later presentation. The findings will be used to inform the development of services and to help us to understand if interventions to reduce later terminations could be developed.

Research Team

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Study sites

NHS Lothian – Chalmers Centre, 2a Chalmers Street, Edinburgh EH3 9ES and Royal Infirmary of Edinburgh, 51 Little France Crescent , Edinburgh EH16 5SU

NHS Greater Glasgow & Clyde – Sandyford Central, 2-6 Sandyford Place, Glasgow, G3 7NB

NHS Highland – Gynaecology Clinic, Raigmore Hospital, Old Perth Road, Inverness, IV2 3UJ

NHS Ayrshire & Arran – The Gatehouse, Ayrshire Central Hospital, Kilwinning Road, Irvine KA12 8SS

NHS Grampian - Square 13 @ Denburn, Denburn Health Centre, West Wing, Room 5, Rosemount Viaduct, Aberdeen AB25 1QB

Background

The legal limit for abortion in Great Britain is 24 weeks (except to prevent grave permanent injury to the physical or mental health of the pregnant woman, to save the life of the pregnant woman or for severe foetal abnormality). However, the provision of later termination of pregnancy varies between NHS boards in Scotland and most do not provide abortion after 18 weeks gestation (unless for the above exception). Currently, other women requesting termination after 18 weeks have to travel to England for the procedure, normally at a British Pregnancy Advisory Service (BPAS), or Marie Stopes International (MSI), clinic. Early termination is preferable to reduce the possibility of physical complications and the NHS Healthcare Improvement Scotland standard is that 70% of women seeking terminations of pregnancy should undergo the procedure at less than 9 completed weeks (i.e. less than 63 days) gestation.¹ The number of abortions in Scotland has decreased in recent years, and the proportion performed early has increased, but further research to shed light on the experiences of women presenting for later termination could help to inform service delivery and intervention development.

In 2010, only 149 of 12826 abortions carried out in Scotland were at estimated 18+ weeks gestation.² However, it has become apparent that this figure represents terminations carried out in Scotland for foetal abnormalities and/or maternal health risks and does not include those women referred to English clinics. Estimates suggest figures for the latter could involve around 120 women annually (based on reports from NHS boards for 2010/11 for women at 16+ weeks gestation). Furthermore, there is anecdotal evidence to suggest that this number represents around half of the women who present for later termination, with the accompanying expectation that the remainder do not proceed with a termination and instead continue with the pregnancy for a variety of reasons. An audit of requests for later terminations at the Royal Infirmary of Edinburgh in 2009-11 found these women were young (aged less than 25 years) and from relatively deprived areas; only half went on to have a termination.³

There has been relatively limited research in this area, but some common themes around reasons for delays in presentation for terminations are apparent. A recent review of research conducted in England between 2005 and 2007 with women presenting for terminations after 12 weeks gestation noted that delays can be service-related, including delays in referral and problems of access (especially beyond 16 weeks gestation).⁴ Later abortions, more often performed at private clinics, encountered further problems, when the distance to a clinic and the need to travel presented a significant barrier. A specific concern for this proposal is whether service-related delays are a particular issue for women in Scotland, especially those who do not proceed with a termination, given their need to travel to England for terminations after 18 weeks gestation.

However, the review goes on to highlight that other reasons for delays in presentation are women-related, much of which occur prior to initial requests for abortion, including delays in realising or recognising pregnancy, denial, ambivalence about having an abortion, concerns about what is involved, relationships with partners (and parents), and changes in life circumstances.⁴ Indeed, a study of women attending two MSI clinics for termination at 19-24 weeks gestation found that it was a combination of factors, both service- and women-related, that led to later presentation.⁵ In the main study reported on in the review (a survey of 883 women attending eight BPAS clinics in England for second trimester abortion), most (85%) reported more than one reason for delayed presentation; 71% reported delays in suspecting they were pregnant, 79% reported delays in deciding to have an abortion (once they knew they were pregnant), and 60% reported delays between requesting and obtaining one.^{4 6} The sample in this study included 43% at 18+ weeks gestation, and when compared with women at earlier stages of gestation, the authors reported that the former were more likely to report delays in suspecting and confirming their pregnancies and continued menstrual bleeding, but also some obstruction from the person first asked for an abortion.^{4 6} Young women (< 18 years) were also more likely to present later than older women, often due to denial, fear of what an abortion would involve, or worry about parents' reaction.⁶ This is mirrored in the findings of the MSI research with women at 19-24 weeks gestation, for whom failure to recognise pregnancy, denial, difficulty deciding to have the abortion, negative impact on partners and/or existing children, and problems of access were all reported as reasons for later presentation.⁵

Rationale

The studies described above highlight the complex, multi-faceted, and often individual nature of women's reasons for later terminations of pregnancy.⁴⁻⁶ However, none has included a focus on the experiences of women from Scotland (although they could well have included, but not reported on, women from Scotland). Nor do the studies focus on the experiences of those who initially request, but do not proceed with, later termination; a particular interest of this proposal, given that only around half of women presenting for later termination appear to go ahead and have the termination in England. Interestingly, in the MSI study, most said that being unable to access the service would have caused them significant emotional trauma and some expressed considerable concern about having to bring an 'unwanted child into the world' if they had been unable to have the abortion.⁵ Detailed study of the experiences, social circumstances, and the reasons behind the decisions of both groups of women is required. This research is vital in order for services to gain an in depth understanding of women at an extremely difficult time in their lives, and to ensure that services support women most effectively, whatever decision they take.

Aim

The aim of the study is to explore the experiences of women in Scotland presenting later for termination of pregnancy and to inform service delivery and intervention development in this area.

Research questions

The specific research questions the study will address are:

- What are the reasons for women in Scotland presenting for later termination of pregnancy?
- What are the consequences of later presentation?
- What are the experiences of women who travel to England for a termination?
- What are the experiences of women who do not go on to have a termination?
- What are the opportunities for intervention to prevent later termination of pregnancy?

Research Design & Methodology

A prospective audit and qualitative research study with women presenting for later termination of pregnancy at five NHS Health Boards in Scotland.

Recruitment Recruitment will be undertaken at termination of pregnancy clinics at Sandyford (NHS Greater Glasgow & Clyde), Chalmers and Royal Infirmary of Edinburgh (NHS Lothian) Raigmore Hospital (NHS Highland), Ayrshire Central Hospital (NHS Ayrshire & Arran) and Aberdeen (NHS Grampian) over a nine month period. Study recruitment will be facilitated by fully trained clinical staff in each of the participating sites, and supported by the co-investigators.

Sample Women presenting at 16 weeks gestation or above will be eligible to participate. The recruitment centres account for two thirds of the women from Scotland estimated to travel to English BPAS clinics for later terminations. Based on this, and the expectation that only around half of the women who initially present go on to have a termination, we estimate that these clinics could see approximately 120 women in a nine month period. All will be included in the prospective audit.

Inclusion criteria Women presenting for termination of pregnancy at 16 weeks gestation or above requesting a termination of pregnancy under ground C of the Abortion Act 1967 (continuance of the pregnancy would involve risk, greater than if the pregnancy were terminated, of injury to the physical or mental health of the pregnant woman); aged over 16 years; able to read or speak English to the level required for participation; and able to provide informed consent.

Exclusion criteria The following women will be excluded: termination required to prevent grave permanent injury to the physical or mental health of the pregnant woman, to save the life of woman, or for severe foetal abnormality; **termination as a result of sexual coercion**; women aged under 16 years; those unable to read or speak English to the level required for participation; those unable to provide fully informed consent; and/or those who appear overly distressed or agitated during the attendance.

All women who meet the inclusion criteria will be provided with information and invited to participate in the qualitative research study. We aim to recruit a minimum of 30 women (15 who proceed and 15 who do not proceed with a termination). The exploratory nature of this study and the small numbers likely to participate precludes purposive sampling, but we will attempt to recruit women from a range of ages and social backgrounds. Furthermore, given the sensitive nature of the topic, it is not known how willing women will be to participate. The MSI study described above did not detail response rates,⁵ and another (of women terminating pregnancies at various stages of pregnancy) reported completing interviews with one third of those initially recruited (although the authors did not report how many women were approached to achieve this recruitment level).⁷ **Because it is not known how many women will be willing to participate, we will continue to recruit until a maximum of 20 is reached for each group (overall maximum 40 participants). Should this maximum be reached for one group and not the other, recruitment will then be targeted toward the smaller group. Should this occur, some minor modification of study materials would be required (primarily the Information Sheet), and we would therefore submit the relevant amendments to the REC for approval.** We will monitor and review recruitment throughout the study and seek to enhance participation by widening the study to additional clinics or via alternative recruitment methods (e.g. direct advertising), subject to appropriate ethical approval.

Audit The audit will follow on from the NHS Lothian audit,³ but will collect data prospectively on women presenting in each site.

Demographic data of interest will be collected (routine at clinics) including: age, reproductive history, deprivation category (based on postcode area of residence), ethnicity, years of residence in UK, and recent and planned contraceptive use. Data will also be collected on eventual outcome of pregnancy (proceeded to later termination of pregnancy/continued pregnancy). Other routinely collected data from clinics that will be recorded are stages in termination of pregnancy pathway that have been associated with delay (failure to suspect pregnancy, delay in confirming pregnancy, delay in decision to have a termination, delay in request for a termination, delay in referral for a termination).

Audit forms (non identifying patient data) will be completed by the recruiting nurse (or other nurse and/or doctor, as determined by the local co-applicant, and trained by the research team).

The paper audit forms will be faxed, or scanned and sent by encrypted email to the clinical research nurse at NHS Lothian. Audit data from all recruitment sites will be collated and entered into a NHS secure excel database at NHS Lothian. Descriptive statistics, and chi-square tests of significance where appropriate, will be conducted.

The audit will be approved locally at each site by the respective Quality Improvement Team/Clinical Audit Group/R&D Department as appropriate.

Qualitative Study Women will be invited to participate in, and asked to consent to an in-depth interview, which will be arranged and conducted at another time, approximately four weeks after recruitment. Women who are interested in participating will be asked to complete a consent form indicating their agreement to be contacted and, separately, for a confidential or private means of contact (e.g. a personal email address or personal mobile telephone number) and the day and time at which they would prefer to be contacted. The consent forms and contact details will be sealed in separate MRC/CSO SPHSU pre-paid envelopes, collected by the recruiting nurse, and mailed to the MRC/CSO SPHSU Survey Office. Participants will also be given a copy of the consent form (and information sheet) to keep. The contact and consent forms will not include the name of the study to prevent participants from being identified as associated with the study, should these mailings be intercepted. The contact form will request only the first name of the participant. A particular colour of paper and a footnote code will identify the study materials to MRC/CSO SPHSU Survey Office staff.

Women who are interested in the study, but do not wish to consent to participate at the time of their clinic visit, will be given an information sheet and consent form to take away with them. The information sheet will detail how the woman can contact the research team should she decide to participate. A dedicated study website (with a means of confidentially leaving contact details), email address and mobile phone number will be set up. The MRC/CSO SPHSU free phone number will also be available. Any unsolicited calls to the MRC/CSO SPHSU will not be answered with the name of the study.

On receipt of the completed contact and consent forms and/or website/email/telephone enquiries, the Investigator Scientist employed on the study will then contact the potential participants directly to confirm and arrange participation in a qualitative interview at a mutually convenient time and location. For all contacts, the Investigator Scientist will use the MRC/CSO SPHSU mobile phone, the number for which will be given to participants at the time of recruitment. Women who have not yet consented to participate will be asked to do so and return the completed consent from

via post (in a reply paid envelope) or at the time of the interview. Telephone interviews will be offered as an alternative to face to face participation **if necessary**.

The Investigator Scientist will make a maximum of three contact telephone calls to participants and women who express interest in the study to arrange interviews. **No telephone messages are to be left for participants. Personal mobile phones are the preferred method of contact. On making contact, the Investigator Scientist will use her first name only, and will give the name of the study only if/when it is verified that she is speaking with the participant.**

One-to-one interviews will be conducted by the Investigator Scientist. Interviews are expected to last for 60-90 minutes. Data collection will commence as soon as the researcher is in post and fully trained (e.g., in interview techniques for sensitive topics, dealing with ethical issues the study raises, and in the use of the interview schedule). Interviews will be conducted at a site most convenient to the participant, i.e. the original clinic attended, the MRC/CSO SPHSU, their own homes or via telephone. Interview participants will receive a £25 gift token (and travel expenses if incurred). Interviews will be digitally recorded (subject to participant consent).

The interviews will yield detailed, in-depth personal accounts of the women's experiences. The interview will essentially follow the lead of the participant, allowing the woman to talk about the issues that are important to her, with a topic guide being used by the Investigator Scientist to follow up on particular issues or topics that may otherwise be missed. This semi-structured interview schedule will focus on: i) pregnancy/abortion experiences; ii) reasons for later presentation; iii) experience of delays in suspecting pregnancy, seeking abortion, and obtaining abortion; iv) post-abortion care (including physical and emotional wellbeing and contraceptive uptake) for those who proceed to abortion, v) reasons for not proceeding (for those who did not), and vi) experience of reproductive health service use.

Participant contact details and consent forms will be stored separately from interview data. Contact details will be destroyed at the end of the study and consent forms and interview data (recordings and transcripts) will be stored securely for 10 years (in line with MRC policy). Participants will be assigned pseudonyms and all identifying data will be removed from interview recordings and transcripts.

Follow Up Participants will not be followed up beyond the qualitative interview. On completion of the research project, a research summary will be produced and sent to participants who request it. Participants will be informed of the research summary at the end of their interview and those who wish to receive it will be asked to provide a postal or email address for this purpose. This information will be stored securely at MRC/CSO SPHSU and destroyed after the research summary has been sent out.

Data Management & Analysis All of the qualitative interviews will be transcribed in full by professional transcribers, with whom MRC/CSO SPHSU have existing confidentiality agreements. It is anticipated that the response rate will be relatively low and that data transcription and analysis (proceeding case by case) will start with the first interview and be ongoing during the course of data collection, allowing for emergent themes to be identified and explored in future interviews. The transcripts will be read repeatedly and coded for analysis by the Investigator Scientist, with the involvement of the Chief Investigator. Data management will be assisted by using QSR NVivo 9.

Qualitative analysis will be undertaken using 'Framework Analysis' a method of proven validity and reliability where data are coded, indexed and charted systematically, then organised using a matrix or framework.⁸ Constant comparison will be carried out to ensure that the analysis represents all perspectives and negative ('deviant') cases. Analysis will focus on answering the research questions, but with attention to unanticipated issues that arise.

Ethical Considerations

At recruitment, the recruiting nurse (or other nurse and/or doctor as above) will ensure that the individual is fully competent, has sufficient time to read and understand the written and verbal information, has the opportunity to ask questions, and that consent is fully informed. Potential participants will be fully informed verbally and in writing about the implications of involvement, their rights to refuse or change their mind without penalty or explanation, the uses that will be made of the data, storage and access to data, and their rights to have data withdrawn.

It is recognised that this is a very sensitive topic and time in a woman's life. Every effort will be taken to ensure no one feels pressured to participate and the timing of the interview will be dictated by the participant to avoid any distress.

Women will be offered the opportunity to withdraw from the study at any point and those who do participate will be asked at key points during the interview to confirm that they are still happy to proceed. If a participant becomes distressed during an interview, the Investigator Scientist will pause or discontinue the interview. At the end of the interview, further information on sources of support (e.g. counselling, post abortion contraception) will be made available to participants.

Precautions will be taken to protect the health and safety of the Investigator Scientist and a risk assessment will be completed prior to the commencement of data collection. Interviews may be conducted in the women's private homes and the Investigator Scientist will be trained in lone working procedures. The Investigator Scientist will use a personal safety alarm, and will be trained in the use of the MRC's Communicare system when

working alone. The Communicare system allows the Investigator Scientist to provide information about the area they are working in, and anticipated finish time. To ensure their safety, if the Investigator Scientist fails to log off/out from the system when a period of fieldwork is completed, firstly the MRC/CSO SPHSU will be contacted, secondly the named contact for the Investigator Scientist, and finally the police. As part of the Communicare system a 'panic' button facility can be used in an emergency situation such as in the event of the Investigator Scientist feeling threatened. The panic facility enables the police to be alerted, in addition to the MRC SPHSU Survey Manager. These emergency procedures will be put in place to minimise health and safety risks during fieldwork. The Investigator Scientist will also have access to occupational counselling and support should the need arise.

Full ethical approval for the qualitative study will be obtained prior to the study commencing.

All data and information gained will be treated with full confidentiality by the research team and in accordance with the Data Protection Act 1998 and MRC research governance principles.

Timetable Study prep (June – September 2012); 12 months study (October 2012 – September 2013)

	2012							2013								
	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept
Prepare research protocol & materials																
Ethics / NHS R&D approval																
RA recruitment																
RA employment contract																
Project team meetings (one 2 hours meeting every 4 months)		*														
Advisory group meetings (approximate)																
Participant recruitment																
Data collection																
Data analysis																
Writing up																
Reporting & dissemination																

*July project planning will be conducted via telephone & email.

Project Management & Quality Assurance

The project is a collaboration between the MRC/CSO SPHSU, the five NHS boards (NHS Greater Glasgow & Clyde, NHS Lothian, NHS Highland, NHS

Grampian and NHS Ayrshire & Arran) and the West of Scotland Sexual Health Managed Clinical Network.

The Chief Investigator, Lisa McDaid, will provide strategic management of, and have ultimate responsibility for delivering the project. She will line manage the Investigator Scientist, who will conduct the qualitative data collection and analysis. Sharon Cameron will lead on the prospective audit and conduct analysis of the audit data with support from Lisa McDaid.

The co-investigators, Sharon Cameron (NHS Lothian), Audrey Brown (NHS Greater Glasgow & Clyde), Lucy Caird (NHS Highland), Catriona Melville (NHS Ayrshire & Arran), and Gillian Flett (NHS Grampian) will be the lead investigators in their respective NHS board area and will take responsibility for monitoring recruitment and adherence to study protocols.

George Laird, Manager of the West of Scotland Sexual Health Managed Clinical Network, will facilitate the involvement of the National Late Termination of Pregnancy Steering Group, which will act as the Project Advisory Group. The Group has representation from all Scottish NHS boards, meets four times a year, and is chaired by Audrey Brown. Lisa McDaid and the Investigator Scientist will attend the Group meetings during the course of the project to feed back and obtain advice, specifically on recruitment, data interpretation, and project conclusions and recommendations.

Expected Outcomes & Dissemination

This exploratory research study will provide evidence of the needs of Scottish women requesting later termination of pregnancy. The findings will help to inform service delivery, specifically if a Scottish service to provide later termination of pregnancy would be useful, and is expected to contribute to the development of interventions to prevent or reduce later terminations of pregnancy.

In the first instance, a full report of the study findings will be submitted to the Scottish Government's BBV and Sexual Health Team. A brief, accessible, summary of the research will be developed and distributed to all participants (unless requested otherwise) as well as participating clinics. MRC/CSO SPHSU has a strong record of public engagement in science and a communication strategy will be established for the project (under the advice of the MRC Regional Communications Manager). We will adopt a dissemination strategy that ensures that the communities affected by the issues of concern are informed of, and can enter into a dialogue about, the findings of research.

Academic papers addressing the research questions will be prepared and submitted to appropriate peer-review journals, such as BMJ, Contraception and the Journal of Family Planning and Reproductive Healthcare. Our academic outputs will be matched with dissemination across the UK to

relevant policy and advisory groups (e.g., the National Sexual Health & Blood Borne Virus Ministerial Advisory Committee), and at practitioner and scientific conferences, such as the International Federation of Professional Abortion and Contraception Associates' biennial Congress, the Scottish Abortion Care Providers' Annual Meeting, and the Wellbeing in Sexual Health (WISH) annual conference. WISH also host an E-Bulletin which is distributed to stakeholders and can be used to disseminate key findings and recommendations for policy.

Key references

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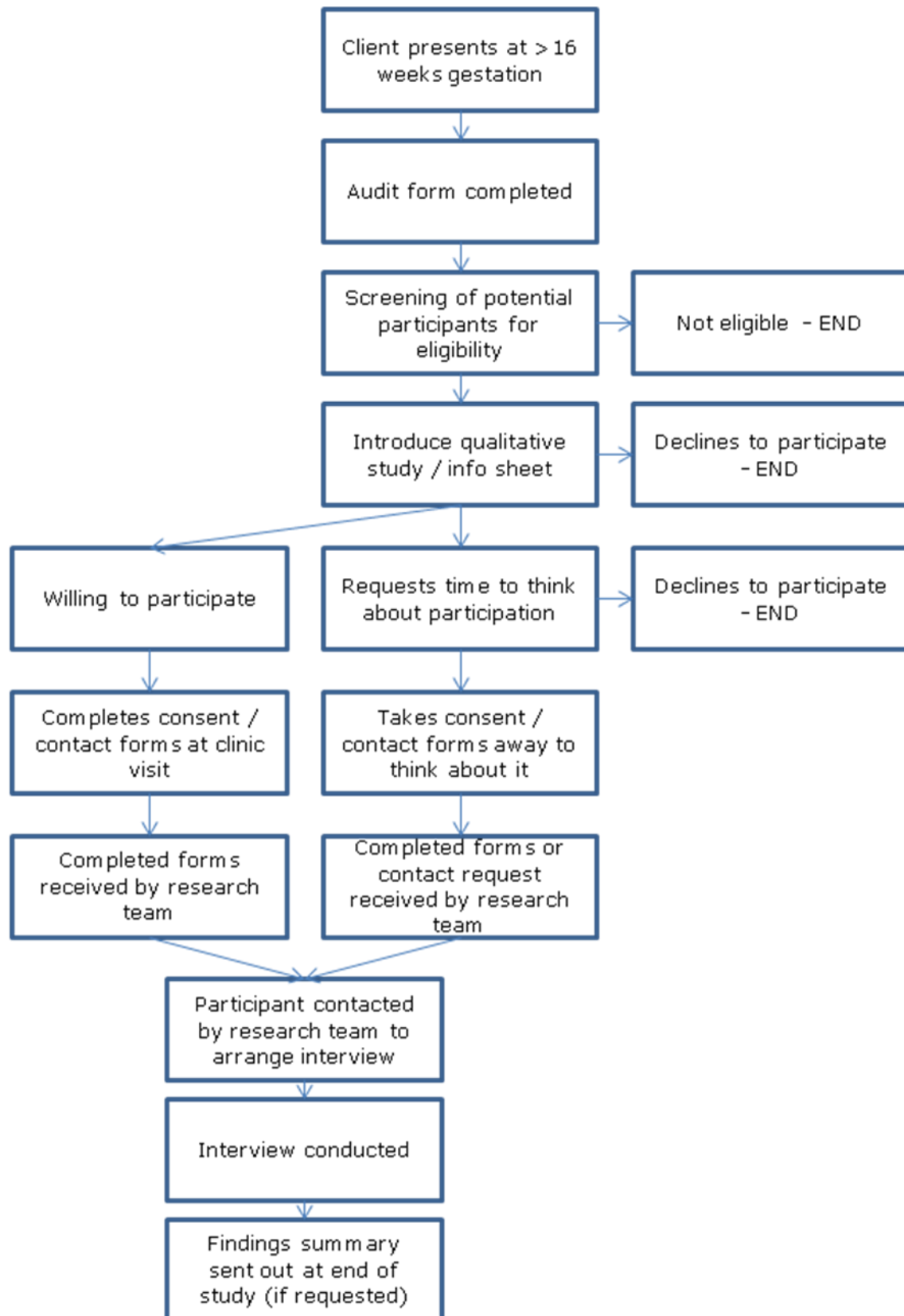


Figure 1: Qualitative Study: Research Protocol Flowchart