Participant Information and Consent Form
Study 1

Principal Investigator:
Dr. Monica Parry, Lawrence S. Bloomberg Faculty of Nursing, University of Toronto
Phone: (416) 946 – 3561
Email: women.heartpain@utoronto.ca

Co-Investigators:
Dr. Hance Clarke - University Health Network
Dr. Ann Kristin Bjørnnes – Oslo Metropolitan University
Dr. Joseph Cafazzo – University Health Network
Ms. Abida Dhukai – University of Toronto
Dr. Paula Harvey – Women's College Hospital
Dr. Joel Katz – York University
Dr. Chitra Lalloo – Hospital for Sick Children
Dr. Marit Leegaard – Oslo Metropolitan University
Dr. France Légaré - Université Laval
Dr. Judith McFetridge-Durdle – Florida State University
Dr. Michael McGillion – McMaster University
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Ms. Rose Patterson – Anishnawbe Health Toronto
Dr. Louise Pilote – Research Institute of the McGill University Health Centre
Ms. Leah Pink – Sinai Health System
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Ms. Carol Auld – Patient Advisor
Ms. Lynn Cooper – Patient Advisor
Ms. Christine Faubert – Patient Advisor
Ms. Deborah Park – Patient Advisor
Ms. Marianne Park – Patient Advisor
Ms. Beatrice Rickard – Patient Advisor
Ms. Vincenza Spiteri DeBonis – Patient Advisor

Title of Project: Development and Usability Testing of HEARTPAIN: An Integrated Smartphone and Web-Based Intervention for Women with Cardiac Pain

Purpose and Background
More women die of coronary artery disease (CAD) than cancer, chronic lower respiratory disease, Alzheimer's disease, and accidents combined. Coronary artery disease is also the leading cause of death of women across all ages, and recent data show an increase in CAD incidence and deaths in

women younger than 55 years of age. Women with CAD have cardiac pain that differs from that of men. The overall goal of this program of research is to develop and assess a HEARTPAIN app and website that will help women self-manage cardiac pain. Feedback from women is a necessary step to designing HEARTPAIN.

Procedures
If I agree to participate in this study, I understand that the following things will happen:

1. I will be asked to complete a baseline demographic form describing my age, education, employment, type and duration of cardiac pain etc. To protect my privacy and confidentiality, I will have a study ID number instead of my name on the form.

2. I will participate in a discussion group session (face-to-face or by free video/web conferencing) for approximately one hour that may involve 4 to 9 other women who have cardiac pain. Their cardiac pain may be similar or different from the cardiac pain that I experience. The session will be audiotaped and to protect my privacy and anonymity, my last name will not be used. All audio and transcribed files will be kept on the secure server at Bloomberg Nursing and only the PI (Parry) and Project Coordinator (Leyden) will have access to the password-protected server. Study data will be kept for seven years and then destroyed.

3. I understand that I can volunteer to participate in the 2-day consensus conference.

4. I understand that I can volunteer to participate in future studies as HEARTPAIN is developed/tested.

Potential Benefits
I understand that by participating in this study that there may be no direct benefits. However, I understand that by participating in this study I may have a better understanding of my cardiac pain. I may also become more aware of cardiac pain in other women.

I understand that I can get a plain language summary of the study results by checking the box below:

- ☐ I would like a copy of a plain language summary of the study results sent to me in an email link.

Potential Risks
I understand that there are no known risks to participating in this study. If I find that the discussion group upsets me, I can discuss this with the researchers who are conducting this study. I can have the option of a one-to-one telephone interview.

If you experience medical distress during a discussion group session, we ask that you let the facilitator know about your distress and medical attention will be sought.

Cost
I understand that there is no charge for participating in this study. I may incur transportation and/or parking costs and these will be reimbursed as outlined in the financial compensation section.

Financial Compensation
I understand that if I need to travel within the GTA to participate in a discussion group my transportation costs will be reimbursed (e.g., TTC tokens, parking), in accordance with University of

Toronto's reimbursement to participant guidelines. I also understand if I attend the 2-day consensus conference that my transportation costs will be covered (e.g., TTC tokens, parking, economy travel), in accordance with University of Toronto's reimbursement to participant guidelines. [Participant guidelines for study reimbursements: http://www.research.utoronto.ca/policies-and-procedures/compensation-and-reimbursement-of-research-participants/]. Original receipts and/or paid invoices will be required before payment is provided.

Confidentiality
I understand that information about specific individuals in this study will be kept strictly confidential and will not be available to anyone except the Principal Investigator (PI) and members of the investigative team. Only an identification number will appear on the demographic questionnaires, and therefore my responses will remain anonymous. One copy of my name and my study identification number will be kept in a locked drawer in the researcher's office. No one but Dr. Parry and the Project Coordinator will have access to the file. All information obtained in this study will be used for research purposes only. I will be able to access the results of the study from the PI when it is complete.
I understand that if I participate in a discussion group, my anonymity will be preserved through the use of my first name only.

I understand that if I participate in a discussion group, my anonymity will be preserved through the use of my first name only.

I understand that I must respect the privacy and confidentiality of other study participants. The names of others involved in this study, and any personal information discussed during the group session are to be kept strictly confidential.

The research study with which you are participating may be reviewed for quality assurance to ensure that required laws and guidelines are followed. If chosen, representatives of the Human Research Ethics Program (HREP), may access study related data and/or consent materials as part of their review. All information accessed by the HREP will be upheld to the same standard of confidentiality that has been stated by the research team.

Right to Refuse or Withdraw
I understand that my participation in this study is entirely voluntary and I am free to refuse to take part in the discussion group or to withdraw at any time prior to the discussion group without penalty. During the discussion group, I also understand that I can choose not to answer any given question without penalty. I understand if I withdraw from the study that my data will only be withdrawn if I explicitly request this to be done. I also understand that during and after the discussion groups, it will not be possible for me to withdraw my data from the study.

Contact
I understand that if I have any questions about the study, I can contact Dr. Monica Parry at 416-946-3561 (Principal Investigator). I understand that if I have questions about my rights as a research participant, I can contact the University of Toronto, Office of Research Ethics at ethics.review@utoronto.ca or 416-946-3273. I may keep this copy of the information and consent letter for my own reference.

SUBJECT STATEMENT AND SIGNATURE SECTION
I have read and understand the consent form for this study. I have had the purposes, procedures and

technical language of this study explained to me. I have been given enough time to consider the above information and to seek advice if I chose to do so. I have had the opportunity to ask questions which have been answered to my satisfaction. I am voluntarily signing this form.

_____ _____

(Signature of participant) (Date)

STATEMENT OF INVESTIGATOR AND SIGNATURE SECTION

I, or one of my colleagues, have carefully explained to the subject the nature of the above research study. I certify that, to the best of my knowledge, the subject understands clearly the nature of the study and demands, benefits, and risks involved to subjects in this study.

_____ _____

(Signature of study personnel) (Date)

Parry M, *et al. BMJ Open* 2020; 10:e033092. doi: 10.1136/bmjopen-2019-033092

Health Care Provider Information and Consent Form
Study 1

Principal Investigator:
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Co-Investigators:
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Ms. Vincenza Spiteri DeBonis – Patient Advisor

Title of Project: Development and Usability Testing of HEARTPAIN: An Integrated Smartphone and Web-Based Intervention for Women with Cardiac Pain

Purpose and Background
More women die of coronary artery disease (CAD) than cancer, chronic lower respiratory disease, Alzheimer's disease, and accidents combined. Coronary artery disease is also the leading cause of

death of women across all ages, and recent data show an increase in CAD incidence and deaths in women younger than 55 years of age. Women with CAD have cardiac pain that differs from that of men. The overall goal of this program of research is to develop and assess a HEARTPAIN app and website that will help women self-manage cardiac pain. Feedback from health care providers is a necessary step to designing HEARTPAIN.

Procedures
If I agree to participate in this study, I understand that the following things will happen:

1. I will be asked to complete a baseline demographic form describing my age, education, and employment etc. To protect my privacy and confidentiality, I will have a study ID number instead of my name on the form.

2. I will participate in an interview session for approximately one hour, which may involve other health care providers who manage women who have cardiac pain. In this session I will be asked to describe the women I see with cardiac pain symptoms, and how I assess, manage and make decisions about their symptoms. The session will be audiotaped and to protect my privacy and anonymity, my last name will not be used.

3. I understand that I can volunteer to participate in the 2-day consensus conference.

4. I understand that I can volunteer to participate in future studies as HEARTPAIN is developed/tested.

Potential Benefits
I understand that by participating in this study I may have a better understanding of how others assess, manage and make decisions about cardiac pain in women. I may also become more aware of cardiac pain and cardiac pain symptoms in women.

I understand that by participating in this study that there may be no direct benefits. However, I may have a better understanding of how others assess, manage, and make decisions about cardiac pain in women. I may also become more aware of cardiac pain and cardiac pain symptoms in women.

I understand that I can get a plain language summary of the study results by checking the box below:

- ☐ I would like a copy of a plain language summary of the study results sent to me in an email link.

Potential Risks
I understand that there are no known risks to participating in this study. However, there may be unforeseeable risks. If I find that the focus group is difficult for me to attend, I can discuss this with the researchers who are conducting this study. I can have the option of a one-to-one telephone interview.

Cost
I understand that there is no charge for participating in this study.

Financial Compensation
I understand there is no financial compensation provided for participation in this study.

Confidentiality
I understand that information about specific individuals in this study will be kept strictly confidential and will not be available to anyone except the Principal Investigator (PI) and members of the investigative team. Only an identification number will appear on the demographic questionnaires, and therefore my responses will remain anonymous. One copy of my name and my study identification number will be kept in a locked drawer in the researcher's office. No one but Dr. Parry and the Project Coordinator will have access to the file. All information obtained in this study will be used for research purposes only. I will be able to access the results of the study from the PI when it is complete.

I understand that if I participate in a discussion group, my anonymity will be preserved through the use of my first name only.

I understand that I must respect the privacy and confidentiality of other study participants. The names of others involved in this study, and any personal information discussed during the group session are to be kept strictly confidential.

The research study with which you are participating may be reviewed for quality assurance to ensure that required laws and guidelines are followed. If chosen, representatives of the Human Research Ethics Program (HREP), may access study related data and/or consent materials as part of their review. All information accessed by the HREP will be upheld to the same standard of confidentiality that has been stated by the research team.

Right to Refuse or Withdraw
I understand that my participation in this study is entirely voluntary and I am free to refuse to take part in the discussion group or to withdraw at any time prior to the discussion group without penalty. During the discussion group, I also understand that I can choose not to answer any given question without penalty. I understand if I withdraw from the study that my data will only be withdrawn if I explicitly request this to be done. I also understand that during and after the discussion groups, it will not be possible for me to withdraw my data from the study.

Contact
I understand that if I have any questions about the study, I can contact Dr. Monica Parry at 416-946-3561 (Principal Investigator). I understand that if I have question about my rights as a research participant, I can contact the University of Toronto, Office of Research Ethics at ethics.review@utoronto.ca or 416-946-3273. I may keep this copy of the information and consent letter for my own reference.

SUBJECT STATEMENT AND SIGNATURE SECTION
I have read and understand the consent form for this study. I have had the purposes, procedures and technical language of this study explained to me. I have been given enough time to consider the above information and to seek advice if I chose to do so. I have had the opportunity to ask questions which have been answered to my satisfaction. I am voluntarily signing this form.

_____ _____
(Signature of participant) (Date)

STATEMENT OF INVESTIGATOR AND SIGNATURE SECTION

I, or one of my colleagues, have carefully explained to the subject the nature of the above research study. I certify that, to the best of my knowledge, the subject understands clearly the nature of the study and demands, benefits, and risks involved to subjects in this study.

_____ _____

(Signature of study personnel) (Date)

Participant Information and Consent Form
Study 2

Principal Investigator:
Dr. Monica Parry, Lawrence S. Bloomberg Faculty of Nursing, University of Toronto
Phone: (416) 946 – 3561
Email: women.heartpain@utoronto.ca

Co-Investigators:

Dr. Hance Clarke - University Health Network
Dr. Ann Kristin Bjørnnes – Oslo Metropolitan University
Dr. Joseph Cafazzo – University Health Network
Ms. Abida Dhukai – University of Toronto
Dr. Paula Harvey – Women's College Hospital
Dr. Joel Katz – York University
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Ms. Beatrice Rickard – Patient Advisor
Ms. Vincenza Spiteri DeBonis – Patient Advisor

Title of Project: Development and Usability Testing of HEARTPAIN: An Integrated Smartphone and Web-Based Intervention for Women with Cardiac Pain

Purpose and Background

More women die of coronary artery disease (CAD) than cancer, chronic lower respiratory disease, Alzheimer's disease, and accidents combined. Coronary artery disease is also the leading cause of

death of women across all ages, and recent data show an increase in CAD incidence and deaths in women younger than 55 years of age. Women with CAD have cardiac pain that differs from that of men. The overall goal of this program of research is to develop and assess a HEARTPAIN app and website that will help women self-manage cardiac pain. Feedback from women is a necessary step to designing HEARTPAIN.

Procedures
If I agree to participate in this study, I understand that the following things will happen:

1. I will be asked to complete a baseline demographic form describing my age, education, employment, type and duration of cardiac pain etc. To protect my privacy and confidentiality, I will have a study ID number instead of my name on the form.

2. I will be asked to use the HEARTPAIN app and website as I work through cardiac pain scenarios and describe my experiences with HEARTPAIN. I will be observed during the session that will last for 1-1.5 hours and take place in a quiet room at the Centre for Global eHealth Innovation. At the end of the session I will be asked four short questions and asked to complete a short questionnaire. The session will be video and audio-recorded and to protect my privacy and anonymity, my last name will not be used. All video/audio and transcribed files will be kept on the secure server at Bloomberg Nursing and only the PI (Parry) and Project Coordinator (Leyden) will have access to the password-protected server. Study data will be kept for seven years and then destroyed.

3. I understand that I can volunteer to participate in future studies as HEARTPAIN is developed/tested.

Potential Benefits
Although there is no guarantee of direct benefits, I do understand that by participating in this study that I may have a better understanding of my cardiac pain.

I understand that I can get a plain language summary of the study results by checking the box below:

- ☐ I would like a copy of a plain language summary of the study results sent to me in an email link.

Potential Risks
I understand that there are no known risks to participating in this study. However, there may be unforeseeable risks. If I find that s cardiac pain scenario upsets me, I can discuss this with the researchers who are conducting this study. A mutually agreeable alternative scenario will be given to me.

If you experience medical distress during a scenario session, we ask that you let the facilitator know about your distress and medical attention will be sought.

Cost
I understand that there is no charge for participating in this study. I may incur transportation, parking and/or out-of-pocket costs and these will be reimbursed as outlined in the financial compensation section.

Financial Compensation

I understand that my transportation and out-of-pocket expenses will be reimbursed, in accordance with University of Toronto's reimbursement to participant guidelines. Out-of-pocket expenses include, but are not limited to: ground transportation to/from session, accommodation if necessary, meals as required. [Participant guidelines for study reimbursements: http://www.research.utoronto.ca/policies-and-procedures/compensation-and-reimbursement-of-research-participants/]. Original receipts and/or paid invoices will be required before payment is provided.

If the study results in the commercialization of this intervention, I understand that I will not be entitled to any financial benefits resulting from it.

Confidentiality
I understand that information about specific individuals in this study will be kept strictly confidential and will not be available to anyone except the Principal Investigator (PI) and members of the investigative team. Only an identification number will appear on the demographic questionnaires, and therefore my responses will remain anonymous. One copy of my name and my study identification number will be kept in a locked drawer in the researcher's office. No one but Dr. Parry and the Project Coordinator will have access to the file. All information obtained in this study will be used for research purposes only. I will be able to access the results of the study from the PI when it is complete.

The research study with which you are participating may be reviewed for quality assurance to ensure that required laws and guidelines are followed. If chosen, representatives of the Human Research Ethics Program (HREP), may access study related data and/or consent materials as part of their review. All information accessed by the HREP will be upheld to the same standard of confidentiality that has been stated by the research team.

Right to Refuse or Withdraw
I understand that my participation in this study is entirely voluntary and I am free to refuse to take part in the usability testing or to withdraw at any time prior to the usability testing without penalty. During the usability testing, I also understand that I can choose not to answer any given question without penalty. I understand if I withdraw from the study that my data will only be withdrawn if I explicitly request this to be done. I also understand that during and after the usability testing, it will not be possible for me to withdraw my data from the study.

Contact
I understand that if I have any questions about the study, I can contact Dr. Monica Parry at 416-946-3561 (Principal Investigator). I understand that if I have question about my rights as a research participant, I can contact the University of Toronto, Office of Research Ethics at ethics.review@utoronto.ca or 416-946-3273. I may keep this copy of the information and consent letter for my own reference.

SUBJECT STATEMENT AND SIGNATURE SECTION
I have read and understand the consent form for this study. I have had the purposes, procedures and technical language of this study explained to me. I have been given enough time to consider the above information and to seek advice if I chose to do so. I have had the opportunity to ask questions which have been answered to my satisfaction. I am voluntarily signing this form.

_____ _____
(Signature of participant) (Date)

STATEMENT OF INVESTIGATOR AND SIGNATURE SECTION

I, or one of my colleagues, have carefully explained to the subject the nature of the above research study. I certify that, to the best of my knowledge, the subject understands clearly the nature of the study and demands, benefits, and risks involved to subjects in this study.

_____ _____

(Signature of study personnel) (Date)

Participant Information and Consent Form
Study 3

Principal Investigator:
Dr. Monica Parry, Lawrence S. Bloomberg Faculty of Nursing, University of Toronto
Phone: (416) 946 – 3561
Email: women.heartpain@utoronto.ca

Co-Investigators:

Dr. Hance Clarke - University Health Network
Dr. Ann Kristin Bjørnnes – Oslo Metropolitan University
Dr. Joseph Cafazzo – University Health Network
Ms. Abida Dhukai – University of Toronto
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Title of Project: Development and Usability Testing of HEARTPAIN: An Integrated Smartphone and Web-Based Intervention for Women with Cardiac Pain

Purpose and Background

More women die of coronary artery disease (CAD) than cancer, chronic lower respiratory disease, Alzheimer's disease, and accidents combined. Coronary artery disease is also the leading cause of

death of women across all ages, and recent data show an increase in CAD incidence and deaths in women younger than 55 years of age.Women with CAD have cardiac pain that differs from that of men. The overall goal of this program of research is to develop and assess a HEARTPAIN app and website that will help women self-manage cardiac pain. Feedback from women is a necessary step to designing HEARTPAIN.

Procedures
If I agree to participate in this study, I understand that the following things will happen:

1. I will be asked to attend one in-person session to learn about the study, provide consent, and complete a baseline demographic form describing my age, education, employment, type and duration of cardiac pain etc. To protect my privacy and confidentiality, I will have a study ID number instead of my name on the form.

2. I will be asked to complete two questionnaires that relate to my pain and health-related quality of life. In addition, I will be asked to fill out these same questionnaires at the end of the 3-month study. To protect my privacy and confidentiality, I will have a study ID number instead of my name on the questionnaires.

3. I understand that there will be two groups of participants in this study: HEARTPAIN group and a control group. I will be randomly assigned (e.g., like flipping a coin) to one of these two groups. I understand that if I am assigned to the control group, I will receive the usual care and supports given to women with cardiac pain, including usual clinic appointments and follow-up. If I am assigned to the HEARTPAIN group, I will also receive the usual care and supports given to women with cardiac pain, including usual clinic appointments and follow-up. In addition, I will log-in to the pain diary app daily for 3 months to complete pain diary entries and develop and track my goals. I can also use the HEARTPAIN website to learn more about cardiac pain.

4. To ensure privacy, all my personal information (e.g., name, address, phone number) will be stored separately from the health data (e.g., risk factors, pain descriptors) that I enter on the HEARTPAIN app/website. Information that is entered in the smartphone app/website or used by the reporting system will be separate from my personal information (e.g., name, address, phone number). No personal information (e.g., name, address, phone number) will be transmitted. For security issues, I will access the app/website using a study number and all health information that is transmitted will be sent securely through an encrypted HTTPS connection that prevents interception by a third party.

5. I understand that my attendance in the HEARTPAIN study is not meant to replace my regular ongoing health care. I should not change any aspect of my regular treatment without first talking to my doctor.

6. I understand that I can volunteer to participate in future studies as HEARTPAIN is developed/tested.

Potential Benefits
I understand that by participating in this study I may have a better understanding of my cardiac pain.

I understand that I can get a plain language summary of the study results by checking the box below:

☐ I would like a copy of a plain language summary of the study results sent to me in an email link.

Potential Risks
I understand that there are no known risks to participating in this study. However, there may be unforeseeable risks. If I find that it is difficult for me to attend the in-person session, I can discuss this with the researchers who are conducting this study.

If you experience medical distress during the three-month app trial phase, please contact your local family doctor. If your medical distress is urgent, please call 911.

Cost
I understand that there is no charge for participating in this study. I may incur transportation, parking and/or out-of-pocket costs and these will be reimbursed as outlined in the financial compensation section.

Financial Compensation
I understand that if I need to travel to attend the in-person session my transportation costs will be reimbursed, in accordance with University of Toronto's reimbursement to participant guidelines. I also understand that a gift card will be provided at study completion ($25). [Participant guidelines for study reimbursements: http://www.research.utoronto.ca/policies-and-procedures/compensation-and-reimbursement-of-research-participants/]. Original receipts and/or paid invoices will be required before payment is provided. If I am assigned to the HEARTPAIN group I will log-in to the pain diary app daily for 3 months to complete pain diary entries and develop and track my goals. This will be done using a Smartphone. If I need a Smartphone to participate in the study, one will be provided for the duration of the study. The study will also pay for data on the phone ($85 each month). If the Smartphone gets lost/stolen/broken during the 3-month study, it will be replaced at no charge.

If the study results in the commercialization of this intervention, I understand that I will not be entitled to any financial benefits resulting from it.

Confidentiality
I understand that information about specific individuals in this study will be kept strictly confidential and will not be available to anyone except the Principal Investigator (PI) and members of the investigative team. Only an identification number will appear on the demographic questionnaires, and therefore my responses will remain anonymous. One copy of my name and my study identification number will be kept in a locked drawer in the researcher's office. No one but Dr. Parry and the Project Coordinator will have access to the file. All information obtained in this study will be used for research purposes only. I will be able to access the results of the study from the PI when it is complete.

The research study with which you are participating may be reviewed for quality assurance to ensure that required laws and guidelines are followed. If chosen, representatives of the Human Research Ethics Program (HREP), may access study related data and/or consent materials as part of their review. All information accessed by the HREP will be upheld to the same standard of confidentiality that has been stated by the research team.

Right to Refuse or Withdraw
I understand that my participation in this study is entirely voluntary and I am free to withdraw at any time without penalty. I also understand that I can choose not to answer any given question without penalty. I understand if I withdraw from the study that my data will only be withdrawn if I explicitly

request this to be done. I also understand that after I receive my group assignment, it will not be possible for me to withdraw my data from the study.

Contact

I understand that if I have any questions about the study, I can contact Dr. Monica Parry at 416-946-3561 (Principal Investigator). I understand that if I have question about my rights as a research participant, I can contact the University of Toronto, Office of Research Ethics at ethics.review@utoronto.ca or 416-946-3273. I may keep this copy of the information and consent letter for my own reference.

SUBJECT STATEMENT AND SIGNATURE SECTION

I have read and understand the consent form for this study. I have had the purposes, procedures and technical language of this study explained to me. I have been given enough time to consider the above information and to seek advice if I chose to do so. I have had the opportunity to ask questions which have been answered to my satisfaction. I am voluntarily signing this form.

_____ _____

(Signature of participant) (Date)

STATEMENT OF INVESTIGATOR AND SIGNATURE SECTION

I, or one of my colleagues, have carefully explained to the subject the nature of the above research study. I certify that, to the best of my knowledge, the subject understands clearly the nature of the study and demands, benefits, and risks involved to subjects in this study.

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(Signature of study personnel) (Date)

Parry M, *et al. BMJ Open* 2020; 10:e033092. doi: 10.1136/bmjopen-2019-033092