Participant Information Sheet/Consent Form

Masada Private Hospital

Title:	Is CB-ART a useful resource for women admitted to Masada Private Hospital MBU? Assessing feasibility, acceptability and usefulness in a pilot study.
Short Title:	Cognitive Behavioural and Art-based program (CB-Art): A pilot study in an early parenting centre

Cognitive Behavioural and Art-based program (CB-Art):

A pilot study in an early parenting centre

Investigators:	Dr Hilary Brown Dr Heather Rowe Professor Jane Fisher
Location:	Masada Private Hospital Mother-Baby Unit (MPHMBU)

Part 1 What does my participation involve?

1 Introduction

Most women admitted to Masada Private Hospital Mother-Baby Unit (MPHMBU) with their unsettled babies are exhausted and distressed. CB-ART is a new program, which is designed to assist women to manage distressing thoughts and emotions. All women admitted to MPHMBU between 17th August 2015 and 14th September 2015 are being invited to participate in a pilot study to see whether CB-ART program might be a helpful addition to the MPHMBU program.

This Participant Information form tells you about the research project. It explains what is involved to help you decide if you want to take part.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or the MPHMBU staff.

Participation in this research is voluntary. If you don't wish to take part, you don't have to.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- understand what you have read;

- consent to take part in the research project;
- consent to be involved in the CB-ART program;
- consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

2 What is the purpose of this research?

Cognitive Behaviour Therapy (CBT) is a well-established psychological therapy to help people recognise and manage unhelpful thoughts. Drawing has been found to be an effective way of assisting this process and helping people to understand their ways of thinking and the consequences for their emotions.

CB-ART is a novel program that combines components of CBT and art. CB-ART aims to improve awareness of thinking styles and of how these can be changed to assist with problem-solving and reduce experiences of feeling powerless and distressed.

This research project is to investigate whether CB-ART might be a useful addition to the MPHMBU program. This research is funded by a Monash-Ben-Gurion seed grant. It is an international collaboration between investigators from the Jean Hailes Research Unit at Monash University and the creators of CB-ART from Ben-Gurion University of the Negev in Israel.

3 What does participation in this research involve?

All mothers admitted to the Masada Private Hospital Mother-Baby Unit (between 17th August 2015 and 14th September 2015) are eligible to participate in this study.

Participation in this research involves the following:

<u>During your stay at the MPHMBU</u>

- Completing a brief survey, which includes some questions about your background and usual ways of thinking. It is estimated that the survey will take 5-10 minutes to complete.
- Attend two one-hour group art sessions during your admission. The sessions will involve some simple drawing activities and a discussion, which will be facilitated by Jane Fisher. She is a Clinical Psychologist who has worked at the MPHMBU since it opened in 1996.

<u>One week after your stay at the MPHMBU</u>

- You will be invited to participate in a short interview by telephone. This will involve completing some of the same questions as in the brief background survey and some about how you are feeling. We would also like your opinions about CB-ART and whether it might be a useful addition to the MPHMBU program. It will take approximately 15 minutes.

<u>Permission to draw limited information from your MPHMBU medical record</u>

- In order to minimise the time spent filling in surveys, we would like your permission to take some information from the forms that you completed before your were admitted to the MPHMBU and before you went home.

There are no costs associated with participating in this research project, nor will you be paid. The CB-ART program is being provided free of charge.

If you are interested, a summary of the results of the research project will be sent to you.

4 Other relevant information about the research project

We expect that about 12 women (four per week for about admission three weeks) will participate in this research project.

5 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project until data analysis has begun which will be about a week after the telephone interview. If you decide to leave the project and you do not want the researchers to keep information you have already given, please tell them before you withdraw. Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your care at MPHMBU in any way.

6 What are the alternatives to participation?

This pilot project is an optional addition to the full program at MPHMBU. You do not have to participate in it.

7 What are the possible benefits of taking part?

As this is a pilot project we do not know whether there will be benefits to participating in it. Women who have participated in CB-ART elsewhere have described it as enjoyable and helpful.

8 What are the possible risks and disadvantages of taking part?

We do not think that there are risks in taking part in this research. The only inconvenience to you is the time taken to complete the survey, the follow up telephone interview and to participate in the two groups. You will not be asked to talk about any personal information that makes you uncomfortable. If you want to discuss the experience of participating in the groups, the researchers or the MPHMBU staff will be pleased to do this.

9 What happens when the research project ends?

If you request it, a summary of the results of the research project will be sent to you, early in 2016.

Part 2 How is the research project being conducted?

10 What will happen to information about me?

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law. Your name and other personal details will be stored separately from the data collected in the survey. We will give your information a unique code number in order to preserve your privacy. You are asked to use this code number and not your name on the survey. All data including (if you give permission) the limited information from your medical record will be entered under a code number and not your name.

The surveys will be stored in a locked filing cabinet and the data in password-protected computer folders accessible only to the authorised researchers at Monash University until five years after publication of the research, when it will be destroyed.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. The results of this study will also be reported by Hilary Brown in her Biomedical Science (Honours) thesis. We will not use your name or any identifying details in any publications, reports or presentations about the research. Only pooled results will be presented.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to request access to the information collected and stored by the research team about you. You also have the right to request that any information with which you disagree be corrected. Please contact a research team member named at the end of this document if you would like to access your information.

11 Who is organising and funding the research?

This research project is being conducted by: Dr Hilary Brown, Professor Jane Fisher and Dr. Heather Rowe from Monash University. This research is funded by a seed grant from the Monash-Ben-Gurion Fund, an international collaboration grant between Monash University and the creators of CB-ART from Ben-Gurion University of the Negev. No member of the research team will receive a personal financial benefit from your involvement in this research project.

12 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the Human Research Ethics Committee of The Avenue Hospital and Monash University.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

13 Further information and whom to contact

The person you may need to contact will depend on the nature of your query.

For further information:
If you want any further information concerning this project or if you have any problems which may be related to your involvement in the project (for example, feelings of distress), you can contact the researchers on:

Name: Dr Hilary Brown
Telephone: 03 99030296
Email:hilary.brown@monash.edu

Name: Professor Jane Fisher
Telephone: 03 99030290
Email:jane.fisher@monash.edu

Name: Dr Heather Rowe
Telephone: 03 99030296
Email:heather.rowe@monash.edu

For complaints:

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Ms Barbara Gogerly
Position: The Avenue Hospital Human Research Ethics Coordinator
Telephone: 9526 5396
Email: hrec.tah@ramsay health.com.au

Consent Form

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Short Title:	Cognitive Behavioural and Art-based program (CB-Art): A pilot study in an early parenting centre
Investigators:	Professor Jane Fisher Dr Heather Rowe Ms Hilary Brown
Location:	Masada Private Hospital Mother-Baby Unit (MPHMBU)

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print)…….....

Signature……..... Date……....

Name of Witness (please print)…….....

Signature……..... Date……....

I agree to the researchers accessing my Masada Private Hospital Mother-Baby Unit records as outlined in Section 3 of this Participant Information and Consent Form.

[ ] YES
[ ] NO

Name of Participant (please print)……

Signature……..... Date……....

Name of Witness (please print)…….....

Signature……..... Date……....

Declaration by Researcher

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Researcher (please print)……

Signature……..... Date……....

Name of Witness (please print)…….....

Signature……..... Date……....

Note: All parties signing the consent section must date their own signature.