Trial of **H**ealthy **R**elationship **I**nitiatives for the **V**ery **E**arly-

PRACTITIONER RECRUITMENT TO TRIAL
INFORMATION SHEET and CONSENT FORM

The THRIVE Trial is funded by the National Institute for Health Research's Public Health Programme.

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Practitioner information sheet

We would like to invite you to take part in the THRIVE Trial. Before you decide whether or not to take part we would like to explain why you have been asked to take part and what taking part will involve.

What is the study about?

There are a number of parenting support programmes running in Scotland that are designed to improve the health and wellbeing of mothers and their babies. This study will compare the efficacy and cost-effectiveness of two antenatal parenting interventions, Enhanced Triple P for Baby (ETPB) and Mellow Bumps (MB) against the normal antenatal care provided during pregnancy, namely Care As Usual (CAU). We are also interested in finding out if any initial benefits carry on as the infant grows. ETPB and MB both aim to reduce child maltreatment by improving mother's understandings of child development and promoting positive parenting skills; however, they do this in different ways. ETPB focuses upon teaching parenting skills, managing expectations about parenthood and teaching coping skills to help mothers meet the challenges of parenting a new baby, whilst MB focuses upon reducing maternal stress, promoting a healthy mother-infant bond and encouraging responsive, nurturing parenting practices. A rigorous evaluation of these two parenting programmes may help health and social care professionals offer the right kind of support to improve maternal mental health, mother-child interaction and promote language development in infants.

What are the interventions?

ETPB for baby is informed by social learning theory. It consists of 4 antenatal group sessions (2 hours each) and 3 individual postnatal sessions (up to 1 hour each) followed by a final group support session (2 hours).. The intervention lasts approximately 13 hours in total. ETPB's emphasis is on families and includes fathers in the sessions. It has a very practical skills-based content around expectations of, and coping with, the new challenges of parenthood whilst maintaining a happy family.

MB is underpinned by attachment theory. It involves seven antenatal groups sessions and one postnatal group sessions lasting approximately two hours each. Fathers are invited to attend one antenatal session. The programme focuses on the mothers' attachment with her foetus/baby. There is an emphasis on nurturing mothers' self care, providing mothers with guided reflection, encouraging nurturing of her foetus/baby, engagement with the foetus/baby and synchrony in the mother-foetus/infant relationship.

Why have I been asked to take part?

You have been asked to take part in the research because you either are experienced or would like to gain experience in working with vulnerable woman. We would like to speak to the practitioners who are interested in delivering the interventions so that we can assess the value and impact of the training.

Delivering the interventions?

You will deliver the interventions in NHS approved community care locations one day per week.

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What would I have to do if I took part in the trial?

If you were interested in taking part in the trial one of our researchers would arrange to meet you so that they could answer any questions that you might have about it. If you decide to take part you would be asked to complete a consent form.

You would be asked to complete training for your chosen intervention in order to ensure that you feel confident in delivering it to the participants. MB will provide one day of training and ETPB will provide up to5 days. All practitioners trained in ETPB and MB will be invited to become involved in the evaluation of both training systems to assess the effectiveness of the training provided.

Data collection will occur at three time points: pre-training, immediately post-training and following 12 months experience of delivering the interventions. We would collect this information from you via questionnaires. You will also be asked to complete a short checklist after each session in order to keep track of the content.

We would like to conduct interviews a few of the practitioners prior to training and 12 months afterwards where you will be asked questions about your expectations and experiences of taking part in the interventions. In addition we would also like to interview practitioners who faced challenges in their sessions such as high drop-out rates or difficult group dynamics in order to examine the reasons behind such difficulties.

In order to evaluate the women's involvement in the sessions we would like to either video-/audio- record some of the interventions or one of our researchers may observe these sessions as they are delivered. We would only do this is we got full consent from both the practitioners and the participants involved in the study.

Practitioners will be asked to undergo supervision throughout the intervention period.

What will supervision involve?

Both ETPB and MB include a supervision model which involves self-reflection, peer support and clinical supervision with practitioners who are experienced in delivering the interventions. As a key aspect of supervision for ETPB, practitioners' will be asked to review audio-or video-taped samples from intervention sessions to self-evaluate in the context of a professional supportive group of peers. Consent will be sought from the parents involved to audio- or video-record the sessions.

What are the benefits of the study?

Participation may benefit society by helping to provide robust evidence of the effectiveness and cost-effectiveness of these interventions in improving the social and emotional wellbeing of both parents and their children and also in facilitating the children's cognitive development. The trial will provide you with the opportunity to develop professionally as intensive training will be provided for each intervention. Funding will be provided for your caseload to be covered when you are taking part in any aspect of the trial.

Is there a downside to taking part?

We do not expect that taking part will disadvantage you in any way.

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How will the results be used?

We hope to find that Enhanced Triple P for Baby and Mellow Bumps improve maternal mental health and mother-child interaction. We also hope to find that one of the interventions will be more cost-effective at producing these outcomes than the other and will be more beneficial to mothers' than the usual treatment provided by the NHS. This could lead to improvements in services provided to vulnerable pregnant women in the future.

What will happen to the information I supply?

The answers you give will be completely anonymous. However, if we feel that you are putting yourself or those in your care at risk then we will need to inform your line manager. All data will be stored in a locked filing cabinet accessed only by the researcher and authorised persons to check that the study is being carried out correctly. All identifiable information will be stored separately from your questionnaires, also in locked storage.

The video footage taken of you delivering the interventions will also be stored in locked filing cabinets and will only be viewed by members of the research team. An external researcher will look at the video footage to make sure that we are analysing it effectively. At the end of the study all of the video-tapes will be destroyed.

What will happen when the study is complete?

You will be involved in the study for approximately 32months and the study will take up to 5 years to complete. All of the information that you give the researchers will be kept safely by the University of Glasgow or by one of our research partners, at the University of Manchester, Glasgow Caledonian University, the University of Newcastle or the University of Aberdeen. If you give your consent it may be used by other researchers with the University of Glasgow's approval, under the strict rules governing the confidentiality of your information. Your name or any material that might identify you or your baby will never be used or given to anyone.

Once all the data has been collected and analysed, the findings will be written in reports to be published in academic journals and the findings will be presented at conferences. A summary report of the findings will be available for participants at the end of the study.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. If they are unable to help you or you wish to make a complaint about the study, please contact the Institute of Health and Wellbeing, University of Glasgow, Research Support Manager by phone on 0141 357 7500 or you can email at survadmin@sphsu.mrc.ac.uk.

Who is involved in the research?

The research is led by Dr. Marion Henderson and involves researchers based at the University of Glasgow, Glasgow Caledonian University, the University of Aberdeen, the University of Manchester and the University of Newcastle. During the study you will be contacted by researchers based at either the University of Glasgow or Glasgow Caledonian University… You can contact the THRIVE team by telephone on 0800 389 2129 or email sphsu-thrive@glasgow.ac.uk.

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Who has reviewed the study?
This study has been reviewed by West of Scotland Research Ethics Committee (3).

What is the next step?
If you have decided that you would like to take part, you will be asked to sign a consent form. You will then be given the initial questionnaires to complete.

Thank you for considering taking part in this study

Dr. Marion Henderson
Chief Investigator for THRIVE

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CONSENT FORM: Practitioner participation in THRIVE trial
(PARTICIPANT COPY)

Participant ID: ……

Name of Researcher:……

PLEASE READ EACH OF THE STATEMENTS BELOW, INITIAL EACH BOX AND SIGN AT THE BOTTOM IF YOU AGREE

Please inital each box

I confirm that I have read and understand the information sheet version 2.0 11.05.15, have had the opportunity to ask questions and have had these answered satisfactorily	☐
I understand that taking part in the study will involve:	
• Perhaps being audio-/video-recorded or observed by a researcher whilst facilitating the Enhanced Triple P for Baby or Mellow Bumps sessions	☐
• completion of post-session protocol checklists	☐
• completion of a questionnaire	☐
I understand that taking part in the study <u>may</u> involve being asked to participate in a one-to-one interview with a member of the research team about my experience of taking part in the study and that this interview will be audio-recorded	☐
I consent to my data being retained by the research team and used for the study if I decide that I no longer want to take part in the study	☐
I understand that the information collected in the study will be used in research reports and articles but that my name will <u>not</u> be used	☐
I understand that any information I provide will be treated in the strictest confidence. The information will be held securely in locked filing cabinets, will only be available to those involved in the research process and programme delivery, and will be destroyed according to University of Glasgow best research practice guidelines	☐
I agree to take part in the study	☐

_____	_____	_____
Participant signature	**Date**	**Name in block capitals**
_____	_____	_____
Researcher signature	**Date**	**Name in block capitals**

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CONSENT FORM: Practitioner participation in THRIVE trial

(RESEARCHERS COPY: PLEASE TEAR OUT)

Participant ID: .....

Name of Researcher:.....

PLEASE READ EACH OF THE STATEMENTS BELOW, INITIAL EACH BOX AND SIGN AT THE BOTTOM IF YOU AGREE

Please inital each box

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Participant signature	**Date**	**Name in block capitals**
_____	_____	_____
Researcher signature	**Date**	**Name in block capitals**

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