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Parents and Primary Caregivers Information Sheet

Study Title: Combined treatment of posttraumatic stress and sleep disturbance in school aged children: A feasibility and efficacy study

Short Title: Evaluating a treatment for trauma and sleep in children

Location: Flinders University, Bedford Park Campus

Investigators:

Jessica Paterson [a, b]
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Clinical Psychologist

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A research team led by Associate Professor Jessica Paterson from Flinders University is currently evaluating a combined treatment program for children and adolescents experiencing posttraumatic stress symptoms and sleep disturbance following a traumatic event. We would like to invite you and your child to participate in this research.

Part 1 What does participation involve?

What is this research about?

Children who experience a traumatic event can have different ways of reacting to the event and coping. Some of these reactions can be helpful, and some are not helpful for their long-term social and emotional adjustment. Research has shown that many children who display high levels of distress after experiencing a traumatic event are at risk of developing significant psychological, sleep and emotional difficulties in the long-term if they do not receive support. Current treatments for posttraumatic stress are typically longer than the mental health care plan of 10 sessions per year, making it difficult for children to receive adequate early intervention. Therefore, we are interested in

evaluating treatment options that can address both posttraumatic stress and sleep difficulties within a 10-session framework allowing it to be more affordable and accessible to families.

In the current study, we are evaluating the feasibility and efficacy of a treatment for primary and high school aged children who are suffering from traumatic stress and sleep disturbance after experiencing a traumatic event. If you decide to take part, your child will receive 10 one-hour psychology therapy sessions targeting both their posttraumatic stress symptoms and sleep disturbances to see if this can improve their recovery. This study hopes to improve how children adjust after a traumatic event and will assist mental health professionals learn how to deliver more effective and accessible treatment programs to children.

What does participating in this research involve for you and your child?

To evaluate the treatment, there are a range of interviews and questionnaires that we will ask you and your child to complete at different time points. This will include both you and your child answering some questions that touch upon certain aspects of your child's traumatic experience. You and your child are not obliged to answer all questions and you may skip any that you find you are unable to answer or find too difficult to answer.

Overview of study involvement:

Screening Questionnaire: This will be a set of standard questions about your child's experience and how it has impacted them that will be used to assess whether your child is eligible to participate in the study. This will be completed over the phone with one of our psychologists when you first refer your child for the study. This part of the study will take approximately 30 minutes.

1-Week Prior to Treatment: You and your child will be contacted to arrange an interview, where there will be several questions to be filled out by yourself and by your child about reactions to the stressful event. You will also be given a sleep diary, a sleep monitoring wristwatch and an under-mattress sleep sensor to track your child's sleep for a week prior to treatment. The under mattress sleep sensor is a set-and-forget measure that you can leave in place for the entire research study. With your permission, parts of the interview will be recorded. This taping is done so that we can check that the interviewer is asking the questions in the correct fashion. The interview could take up to 1.5 hours, and it could take up to 1 hour to complete the questionnaires.

Treatment: You and your child will be invited to attend 10 one-hour sessions at the Sleep and Psychology Laboratory at Flinders University over 10 weeks, where your child will receive 4 sessions of Cognitive Behaviour Therapy for insomnia (CBT-i) to address sleep difficulties and 6 sessions of trauma-focused Cognitive Behaviour Therapy (TF-CBT) to address posttraumatic stress. Both CBTi and TF-CBT are recommended evidence-based treatments for sleep and posttraumatic stress, respectively. After the four sessions of treatment for sleep difficulties we will again ask you to complete a sleep diary for your child, and your child to wear a sleep

monitoring wristwatch to track their sleep for a week. We will also ask you to complete some questionnaires (1-2 hours) to track their progress after four weeks. The sleep diary and wristwatch, and questionnaires, will be repeated at the end of therapy (10 weeks) and 3-months after therapy is completed. With your permission the under mattress sleep sensor will track sleep throughout this entire period.

With your permission, therapy sessions will be video recorded to ensure that therapists are delivering the treatment the way it should be delivered. The tapes may be randomly checked by another researcher (who is not directly involved in the study). Please be assured we will be using a secure method of sending any tapes to researchers to maintain confidentiality. Recordings will be stored in a secure and confidential manner and will be destroyed 30 years after the completion of the study.

Parent Information Session: In the first few weeks of the study, parents will be invited to attend a 60-minute online information session to help support you and your child throughout the treatment.

Treatment Completion: We will ask you and your child to fill out a number of questionnaires again (1-2 hours) and complete a short interview with you and your child (30 mins).

Three-Month Follow-Up: Three months after treatment completion, a researcher will contact you via phone to ask some follow-up questions of your child and to arrange additional sleep assessments. These questions will relate to your child's mood and reactions to the stressful event, and your child's sleep will be assessed. We will ask you to fill several questionnaires again (1 hour) and a final interview with your child (30mins). This will help us to determine how effective your child's recovery was from the treatment over time. In addition, carers of older children (13-18y/o) may be asked to participate in an interview regarding their personal wellbeing throughout the program. This is entirely voluntary.

What costs are involved?

There are no additional costs associated with participating in this research project, nor will you be paid. All care required as part of the research project will be provided to you free of charge. Free parking is available at Bedford Park campus, and the campus is accessible via public transport (bus or train). The campus is also wheelchair accessible.

Do I have to take part in this research project?

Participation in this research is voluntary and both you and your child have the right to withdraw from the study at any time. If you or your child decide not to participate in this study or if you withdraw from the study, you may do this freely without prejudice to any treatment at Flinders University.

What are the alternatives to participation?

You do not have to take part in this research project for your child to receive treatment for posttraumatic stress or sleep. Other options are available which can be discussed with your GP or with staff on this research project.

What are the possible benefits of taking part?

Although we cannot predict whether your child will benefit from the treatment offered in this study, children and their parents who have received similar therapies in the past have reported to have gained at least some benefit. In addition, the knowledge gained in this research will help us to provide better services for children who experience difficulties after a traumatic event. At the 3-month follow-up interview, we can discuss possible referrals for additional therapy if you believe this may be helpful.

What are the possible risks and disadvantages of taking part?

Although there is no anticipated risk in participating in the research, at times you or your child may think about experiences that are sensitive or distressing. You and your child will be seeing a trained therapist who is experienced in discussing such matters, and who will help you work through any difficult emotions during the course of therapy. Further, Assessment and Crisis Intervention Services (ACIS; 13 14 65), Lifeline (13 11 14) or Kids Helpline (1800 55 1800) can be contacted at any time should you or your child experience anxiety or distress out of office hours.

Session times are generally available between Monday to Friday between 9am to 5pm, however, the session times can be negotiated dependant on the availability of the therapist. Please note that children may be required to miss an hour of school to attend each session, plus travel time.

What will happen to the information provided by myself and my child?

All records containing personal information will remain confidential and no information that could lead to your identification will be released, except as required by law. All information gathered via questionnaires, interviews and session recordings will be coded with a number and will not include any identifying information that could be linked to you or your child. Hardcopy data will be securely stored for 30 years and will only be accessible to the project researchers. When children turn 18 years of age, they may request any video footage of them as a child to be deleted.

No information that could lead to you or your child's identification will be released without your written consent. However, please note that the researchers and psychologists working on the project are mandatory notifiers, and therefore, they are required to notify the Department for Child Protection if they suspect on reasonable grounds that a child or young person is, or may be, at risk of harm. It is your right to obtain copies of certain parts of information gathered during the research should you wish to do so. However, please be aware that certain materials or information cannot be released if you do not possess the appropriate professional qualifications required for their interpretation. The data gathered through this research may be published in psychological journals, and during this process, may be examined by a third party reviewer. The data may also be presented

at conferences, but you and your child will not be identifiable in any manner in these publications/presentations.

Can my child receive other treatments during this research project?

Whilst your child is participating in this research project, they will not be able to engage in other treatments for posttraumatic stress or sleep. This constraint is imposed because it is important for the investigators to determine whether changes in posttraumatic stress and sleep symptoms are a result of the treatment study, or from another external factor. If this could be a problem, then it can be discussed with the researchers and/or your GP.

What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing. Notifying the researchers will also allow them to assist with finding other treatment options, should this be necessary.

If you or your child do withdraw your consent during the research project, the researchers will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected up to the time you withdraw will form part of the research project results. If you do not want this, you must tell us before you join the research project.

What happens when the research project ends?

Once the project finishes, treatment with a study therapist will no longer be available to you or your child in an ongoing manner. However, during the course of treatment you and your child will be provided with tools and resources that can be utilised independently to maintain progress. In relation to study results, an overall summary of how the study went can be emailed to you if wish when the study is complete. In addition, you and your child will be discussing your child's individual progress during the treatment with the therapist so that you can monitor things in an ongoing way.

Part 2 How is the research project being conducted?

Complaints and Compensation

If you or your child suffer any complications as a result of this research project, you should contact the study team as soon as possible. The study team will endeavour to determine whether the treatment can be modified in order to better suit the needs of you and your child. If this is not possible, you will be assisted with arranging appropriate alternative care. This may involve referral to another psychologist or mental health professional who can provide alternative support. This study has been reviewed by The Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC). Should

you wish to discuss the project with someone not directly involved, in particular in relation to matters concerning policies, your rights as a participant, or should you wish to make a confidential complaint, you may contact the Research Ethics Office on 8204 6453 or at Health.SALHNofficeforresearch@sa.gov.au.

Who is organising and funding the research?

This research project is being conducted by Associate Professor Jessica Paterson and is funded by the Flinders Foundation.

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 Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC). 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. The research is also in line with the Flinders University ethical guidelines.

Further information and who to contact

If you would like more information about the project or have concerns, either before, during or after the study, please contact Associate Professor Jessica Paterson, College of Education, Psychology and Social Work, Flinders University, GPO Box 2100, SA 5001, phone: +61 8 8201 2324, or email: jessica.paterson@flinders.edu.au. If you are in a crisis situation or need to discuss your wellbeing outside of office hours, please contact Assessment and Crisis Intervention Services (ACIS; 13 14 65) or Lifeline (13 11 14). If your child is in a crisis situation, you can also contact Kids Helpline (1800 55 1800).

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	The Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC)
Telephone	08 8204 6453
Email	Health.SALHNOfficeforResearch@sa.gov.au

Thank you for your time in reading this information sheet. Please feel free to take your time in deciding whether you and your child would like to take part in this research.

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I, ... request and give consent to
(first or given names) *(last name)*

my child's involvement in the research project: **Integrated treatment of posttraumatic stress and sleep disturbance in primary school aged children: A feasibility and efficacy study**

I acknowledge the nature, purpose and contemplated effects of the research project, especially as far as they affect my child, have been fully explained to my satisfaction by ..... *(researcher/therapist)* and my consent is given voluntarily.

1. The nature and purpose of the research project described on the attached Information Sheet has been explained to me. I understand it and agree to my child taking part.
2. I understand that I/my child may not directly benefit by taking part in this study.
3. I acknowledge that the possible risks and/or side effects, discomforts and inconveniences, as outlined in the Information Sheet, have been explained to me.
4. I understand that I can withdraw my child from the study at any stage and that this will not affect medical care or any other aspects of my/my child's relationship with this healthcare service.
5. I understand that I can seek external advice and input before providing consent for myself and my child to participate in this study.
6. I give permission to use an actigraphy wristwatch to monitor my child's sleep monitoring at home for three weeks, one time before treatment, one time during treatment, and one time after treatment.
7. I give permission for ongoing sleep tracking of my child via an under-mattress sleep sensor for the duration of the study.
8. I am aware that I should retain a copy of the completed Consent Form, and the Information Sheet.
9. I acknowledge that my child's sessions will be audio/video recorded and I agree to these being provided to the researchers for coding and quality assurance purposes.
10. I understand that my/my child's information will be kept confidential as explained in the information sheet except where there is a requirement by law for it to be divulged.
11. I understand that deidentified, aggregate data from this study may be used for broader purposes than reporting the findings of this study.

Parent/Primary Caregiver Consent

Signed: ..... Dated:.....

Name: ..... Relation to child :.....

Adolescent Consent

Signed: ..... Dated:.....

Name: .....

Therapist/Researcher

I certify that I have explained the study to the participant/parent/guardian and consider that he/she understands what is involved.

Signed: ..... Position: .....

Name: ..... Dated: .....