Title: An investigation of the effectiveness of Parent Management Training (PMT) and Collaborative and Proactive Solutions (CPS) for the treatment of children and adolescents with Oppositional Defiant Disorder

Project Sponsor: Health Psychology Unit, University of Technology Sydney

Principal Investigator: Dr Rachael Murrihy

Site: Health Psychology Unit, UTS, 174 Pacific Hwy, St. Leonards, 2065

Protocol: UTS HREC 2014000159 – MURRIHY

What does my participation in the study involve?

You are invited to take part in “An investigation of the effectiveness of Parent Management Training (PMT) and Collaborative and Proactive Solutions (CPS) for the treatment of children and adolescents with Oppositional Defiant Disorder”, which may be suitable for you. Before you decide if you wish to participate we would like you to understand why the study is being done, what it will involve and how your information will be used. Please take the time to read the following information carefully and, if you wish, discuss it with friends or relatives. One or more of our team will go through the information sheet with you and answer any questions you have. Please ask questions about anything that you do not understand or want to know more about.

1 What is the purpose of this research?

Parent Management Training (PMT; Patterson, 2002) originated in the 1960’s and is currently considered the best psychological treatment for children with behaviour problems (Murrihy, Kidman & Ollendick, 2011). The program trains parents to use strategies to change their child's behaviour (such as consequences and time out). However, PMT does not work for everyone. Research has shown that a significant percentage of children still have behaviour problems when treatment is finished (Dishion & Patterson, 1992). For this reason we need to look at different ways of treating oppositional defiant disorder. Collaborative and proactive solutions (CPS) is a therapy which was developed by Harvard University Medical School and is well known in the United States. CPS is different to PMT as it focuses on addressing skills that the child is lacking and teaches parents and their children shared problem solving.

This year a major research study in the United States compared PMT and CPS and found that both worked equally well in treating child behaviour problems (Ollendick et al., 2014). This research is significant in that we hope to work out whether CPS continues to show positive results for youth with ODD (compared to PMT) when used in ”real world” settings. Also, our study will look at whether this therapy works well with Australian children.

2 Why have I been chosen?

Your family was chosen for this study because your son/daughter has been showing some problem behaviours and fulfils the eligibility criteria for this study.

3 Do I have to take part in the research?

It is up to you to decide whether or not to take part in this study. If you do decide to take part you will be given this Participant Information Sheet and Consent Form to sign and you will also be given a copy to keep. If you decide to take part you can change your mind and withdraw from the study at any stage, for any reason. Your decision not to take part, or take part and then withdraw from the study will not affect your family’s routine treatment or future health care.

4 What will happen to me if my family does take part?

Dr Rachael Murrihy
Health Psychology Unit, UTS
Version 2, 11/07/2014
Parent/s will be asked to sign a consent form before any assessment is conducted. You will be participating in a study where you will be randomly put into one of two treatment groups. This means that each family will have a 50/50 chance of being put in to either the CPS or PMT group. We need to compare the different treatments to see how well they work. To try to make sure the groups are the same to start with, each participant is put into a group by chance (random).

Assessment. Your family will be asked to attend assessment sessions on three occasions. Before treatment starts, at the end of treatment and then 6 months after treatment has finished. Each session will take about 1-2 hours and will involve an interview with a clinician about your child’s current problems as well as questionnaires to fill out. You will be given $100 Coles voucher at the end of the post treatment assessment and again after the 6 month follow-up (maximum $200 in total).

Treatment. Each family will be offered up to 16, one-hour sessions of therapy with an experienced clinical psychologist at our clinic in St. Leonards (near Royal North Shore Hospital). We encourage both parents/guardians to come to each session, however, treatment can go ahead if only one parent can come along. Your child will also have to come to each session. Sessions are weekly. We are not able to pay for travel expenses. However, the therapy is free of charge.

Sessions will be audiotaped with your permission. The purpose of this is to ensure the therapists are implementing the therapy correctly. If you would prefer your sessions not to be taped you can let us know and we’ll respect your wishes.

5 What do I have to do about my child’s medication?
If your child is currently taking any prescription medications they can continue to do so during this study.

6 What if my family doesn’t want to participate in your study but we still want treatment?
Participation in this study is not your only option. If you want PMT, your other options may include seeing a private clinical psychologist or contacting your local community mental health centre. At this stage we are not aware of any services that offer CPS.

7 What are the possible benefits of taking part?
We cannot guarantee that you will receive any benefits from this research, however, our aim is to reduce your child’s problem behaviour.

8 What are the possible disadvantages and risks in taking part?
Based on previous research, we do not believe that participation in our study will cause any harm to your family. However, if there is a big increase in oppositional behaviour your therapist will offer continued support, even if you decide that you do not want to continue in the trial. Families do not have to participate if they don’t want to and there will be no penalty for refusing to participate or withdrawing part way through the trial.

We have carefully designed this project to protect your family’s privacy, and any information collected will be kept confidential. All data collected will be de-identified using numerical codes to protect privacy and will be stored in a confidential way at the Health Psychology Unit.

9 What do I do if I wish to withdraw from the research?
If you wish to withdraw from this study please advise the study team. You will be asked to complete and sign a “Withdrawal of Consent” form, provided to you by the study team. If you do withdraw your consent during the study, the relevant study staff will not collect additional personal information from you, although personal information already collected will be retained, to
ensure the results of the study can be measured properly and to comply with law. You should be aware that data collected by the researcher up to the time you withdraw will form part of the study results. You will be unable to have any data already collected removed.

10 Could this study be suddenly stopped?
Yes, if we get unexpected reactions, such as big increases in aggressive behaviour or the treatment does not work. In the unlikely event that this occurs the chief researcher will tell you as soon as possible. Where possible, we will tell you face-to-face, although if this is not possible (e.g., you are not able to come into our office), we will tell you via phone and sending letters. We will also offer a therapy session to discuss your reaction to treatment finishing.

11 What happens when the study ends?
At the end of the treatment if your family needs further help your therapist can refer you to relevant services in your area. We will ask at the end of treatment whether your family would like to see a summary of the research findings via email or post. Once the study has finished we will write up the results in an article and have them published in a peer-reviewed journal.

12 What will happen to information about me?
When signing the consent form, this means you are allowing members of the study team to collect and use personal information about you and your family for the study project. Your information will only be used for the purpose of this study project and it will only be disclosed with your permission, except as required by law. Data will be kept on file for 7 years before being destroyed. It is expected that the results of this study will be published and/or presented in many different settings. In any publication and/or presentation, information will only be shown in a way so that you cannot be identified.

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

13 What access do I have to information my child shares with the therapist?
If the treating clinical psychologist has any concerns about the safety of your child or harm coming to others in your child’s life, they will discuss this directly with you. Otherwise information shared by the child with the therapists will be kept confidential.

14 What if I have concerns or a complaint?
If you have concerns about the research or experience any distress resulting from therapy you can speak to one of the clinical psychologists at the Health Psychology Unit by calling us on (02) 9514 4077. This research has been approved by the Human Research Ethics Committee of the University of Technology Sydney. If you would like to talk to someone who is not connected with the research, or have any complaints or reservations about any aspect of this research which you cannot resolve with the researcher, you may contact the Research Ethics Officer on (02) 9514 9615, and quote this number (HREC 20154000281).

15 Who is organising and funding the research?
This study is being funded by ongoing supporters of the Health Psychology Unit including: Fairfax Family Foundation, the Hunt Foundation, Peters Family Foundation, Barbara Alice Trust, Fantastic Furniture and Arun Abey.

16 Who has reviewed the study?
All research in Australia involving humans is reviewed by an independent group of people, called a Human Research Ethics Committee (HREC). This study has been reviewed and given approval by UTS Human Research Ethics Committee.

17 Further information and who to contact if I have a complaint?

Dr Rachael Murrihy
Health Psychology Unit, UTS
Version 2, 11/07/2014
If you want further information about the research, have concerns or experience any distress resulting from therapy you can speak to one of the clinical psychologists at the Health Psychology Unit by calling us on (02) 9514 4077. If you would like to talk to someone not directly involved with the study for any further information regarding your rights, or should you wish to make a complaint to people independent of the study team, you may contact the UTS Ethics Secretariat on (02) 9514 9772 and quote this number (HREC 20154000281).

<table>
<thead>
<tr>
<th>Question</th>
<th>Who to contact</th>
<th>Phone / Facsimile</th>
</tr>
</thead>
<tbody>
<tr>
<td>General questions or concerns during the study</td>
<td>Principal Investigator</td>
<td>02 9514 4077</td>
</tr>
<tr>
<td></td>
<td>Dr Rachael Murrihy</td>
<td>02 9514 4390</td>
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<td></td>
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<td><a href="mailto:Rachael.Murrihy@uts.edu.au">Rachael.Murrihy@uts.edu.au</a></td>
</tr>
<tr>
<td>Questions about the way the research is being conducted</td>
<td>Dr Rachael Murrihy</td>
<td>As above</td>
</tr>
<tr>
<td></td>
<td>UTS Ethics secretariat</td>
<td>02 9514 9772</td>
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</tbody>
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Consent Form

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1. I have read the attached Participant Information Sheet outlining the nature and purpose of the research study and I understand what I am being asked to do.

2. I have discussed my participation in this study with the member of the study team named below. I have had the opportunity to ask questions and I am satisfied with the answers I have received.

3. I have been informed about the possible risks of taking part in this study.

4. I freely consent to participate in the research project as described in the attached Participant Information Sheet.

5. I understand that at the post-treatment assessment session I will receive $100 Coles voucher, and I will receive another $100 voucher at the follow-up assessment ($200 in total).

6. I understand that my participation is voluntary and that I am free to withdraw at any time during the study without affecting my future health care.

Name of Participant __________________________ Signature of Participant __________________________ Date ______________

Name of Witness to Participant’s Signature __________________________ Signature of Witness __________________________ Date ______________

Name of Witness to consent process __________________________ Signature of Witness __________________________ Date ______________

Name of Investigator __________________________ Signature of Investigator __________________________ Date ______________

Dr Rachael Murrihy
Health Psychology Unit, UTS
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Withdrawal from study form

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I hereby wish to WITHDRAW my intent to participate further in the above research project and understand that such withdrawal will not jeopardise my future health care.

Participant’s Name (printed)  

Signature

Date

In the event the participant decided to withdraw verbally, please give a description of the circumstances. Coordinating Investigator to provide further information here:

Coordinating Investigator to sign the withdrawal of consent form on behalf of a participant if verbal withdrawal has been given:

Participant’s Name (printed)  

Signature of Investigator

Date
CLIENT CONSENT FOR RECORDING OF SESSIONS

I understand that audiotaping may be used during my sessions to ensure my therapist is delivering the treatment appropriately. I also understand that I will be fully informed prior to any recording which may be undertaken.

All information will remain strictly confidential and will not be released to any person outside the UTS Health Psychology Unit team.

Name: ______________________________________________________
Address: ______________________________________________________

____________________________________________________________

________________________________ Post Code _____________
Signature: ____________________________________________________
Date: _________________________________________________________