



ETHICS PROCESS

Evaluating treatment effectiveness of the Trauma Recovery Network Australia

Prepared for:

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PHASE 2: CONSENT FORM PHASE

ETHICS PROCESS IN TRNA EVALUATION

Rationale

Working according to ethical principles and disclosing them at the outset of an evaluation promotes integrity, honesty and respect in all dealings with stakeholders, evaluation participants and in the use of evaluation data. The following ethical principles are based on the New South Wales Government ethical conduct in evaluation guidelines located on the Evaluation Resource Hub website. Seven key ethical principles are outlined:

- 1) Utility Ensuring the evaluation is worthwhile
- 2) Neutrality Limiting potential bias
- 3) Informed consent & willing participation
- 4) Minimising adverse effects
- 5) Sensitivity towards specific groups and circumstances
- 6) Confidentiality & privacy
- 7) Responsible reporting

Scope & aims

Ethical considerations should be anticipated and addressed while the evaluation protocol is being developed. This is the aim of the current document and is the responsibility of the author. Ethical consideration should then be identified and managed as they arise during the course of implementation of the evaluation. Identifying and managing ethical issues during implementation is outside the scope of this report and the responsibility of the Trauma Recovery Network.

Ethical principles

1) Utility – Ensuring the evaluation is worthwhile

The TRNA evaluation is designed to serve a specific need. That is to evaluate the effectiveness of EMDR in improving trauma, depression and treatment satisfaction. The novel aspect of this evaluation is that it is early intervention in the context of bushfire disaster which is specific to the needs of Australians living in high-risk bushfire areas. The potential benefits of this approach include less economic-costs on the mental health system and improved client outcomes which outweigh the costs of implementing the project.

Ethical principles continued...

2) Neutrality – Limiting potential bias

The TRNA evaluation contracted the author as an external party to conduct evaluation protocol, ethics processes, data cleaning, data analysis and reporting. The TRNA also enlisted Novopsych as the software to administer, interpret and store data. Both these external parties will act independently to the TRNA in their roles of a) evaluation, and b) data storage, respectively. The evaluation questions were developed prior to implementation to ensure the questions asked did not align with positive results after the fact.

3) Informed consent and willing participation

The TRNA has integrated an informed consent process into initial orientation to treatment which is delivered via Novopsych software. Not only does the Novopsych page ask whether consent is provided but also provides information related to the purpose of the evaluation, the nature of how the data will be used, that consent is voluntary as well as the predicted risks and benefits of participation. This information is outlined in Appendix A.

4) Minimising adverse effects

The treatment delivered to clients is not anticipated to have any adverse events. If anything, it is predicted to be improved access and effectiveness than treatment-as-usual. The TRNA has considered the outcome measures used in the evaluation based on a balance of clinical appropriateness and limited burden to the client. As such, the PCL-5 and PHQ-9 were considered to measure appropriate domains whilst containing questionnaires to 29 items which can be completed in under 5 minutes. Similarly, the Client Satisfaction Survey was chosen as a brief 10-item measure of client satisfaction that also captured qualitative information. There is no evidence that the content of questionnaires, relating to mood, trauma or risk, increase the probability of adverse effects to clients.

Ethical principles continued...

5) Sensitivity towards specific groups and circumstances

The measures used in the evaluation are unable to be provided in languages other than English. It is recognised that this may be a barrier to individuals whose first language is not English. In these circumstances, it is recommended treatment is delivered as per usual without administration of the measures. The measures are designed for individuals 18 and older. If an individual presents for treatment who is under 18 years old, it is recommended that treatment is delivered as per usual without administration of the measures. The concept of mental health, trauma, depression and quality assurance activities, such as client satisfaction surveys, may be conceptualised differently to individuals of different cultural, religious or social groups. Administration of outcome measures should be sensitive to the cultural, religious and social needs of the clients.

6) Confidentiality and privacy

All data collected will be stored on Novopsych which uses a high level 256bit encryption and surpass the standards set out by the Australian Privacy Principles. During the data cleaning and data analysis phase, all data will be exported in one instance to reduce frequency of data transfer reducing risks to confidentiality breaches during this process. Data will be stored on a password protected computer only accessible by the author and data will be deleted once the results have been reported to TRNA.

7) Responsible reporting

An evaluation team should be able to demonstrate that their evaluation was conducted ethically and be able to produce evidence to support this claim. This may include explaining how data collection methods were selected and implemented, who took part and how they were invited, and ways in which the data were analysed and reported. This is the responsibility of the author and the TRNA. The author is responsible to developing an evaluation protocol, ethics process, data cleaning/analysis documentation, and final reporting that is transparent and considers the guiding principles of ethical evaluation. The TRNA is responsible for updating these documents during the project implementation if any changes occur that include but are not limited to treatment delivery, outcome measures, using Novopsych or recruitment. The TRNA are also responsible for addressing ethical dilemmas that may arise during the process of project implementation.

APPENDIX A

CONSENT FORM CONTENT

The Trauma Recovery Network Australia is conducting research on the impact of bushfires on mental health, and people's recovery from those fires. Do you consent to anonymous data collected via these questionnaires being used for research purposes?

Yes

No

More information:

Trauma Recovery Network Australia is asking your consent to allow them to use data from questionnaires within treatment in an evaluation to understand whether this treatment is effective. Consent is voluntary. Your agreement to allow use of data from questionnaires will not involve any change in your treatment or any extra effort on your part. Instead, you are giving the Trauma Recovery Network Australia permission to extract data from your questionnaires and put it into a database that does not include your name or any identifying information so that they can understand the effectiveness of treatment. Your questionnaire data will be securely stored in encrypted software called Novopsych or on password-protected desktop computer when data is being analysed.

There are no anticipated risks to clients in providing consent to the evaluation. Similarly, there are no expected benefits to you directly from the evaluation. The results of the evaluation are more likely to benefit individuals in the community as the purpose of this work is to find out the effectiveness of therapy and how to improve treatment for clients to reduce suffering after experiencing trauma.