

Participant Information Sheet

A study of clients' views of the effects of counselling

As someone who has been referred by your GP to counselling at the Tayside Centre for Counselling (TCC) at Abertay University, you are being asked to take part in a research study. Before you decide whether or not you want to take part in this study, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Feel free to talk to others about the study if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. The offer of counselling from the Tayside Centre for Counselling (TCC) does not depend on whether you take part in the study or not.

What is the purpose of the study?

The purpose of the study is to find out more about how people referred by their GPs to a counselling service evaluate the therapy they receive. There have been a number of previous studies of the effectiveness of counselling where patients have been referred by GPs, but none of these studies has looked in detail at what *clients* think and feel about their counselling. The aim of the present study, therefore, is to develop an in-depth understanding of the experiences of service users, with the goal of applying this information to improve services in future.

Why have I been chosen?

All patients referred for counselling to TCC over a 12 month period are being invited to be involved in this study.

Do I have to take part?

No. It is up to you to decide whether or not to take part. If you do decide to take part in the research, you will be given this information to keep, and

be asked to sign a consent form. You are still free to withdraw at any time, and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

What will happen to me if I take part?

As a client of TCC, you will receive up to 12 sessions of counselling in any one year. If you take part in the research study, we will ask you to complete some questionnaires, and a brief audio recorded interview:

- before you commence counselling
- immediately after you have completed counselling
- at follow-up – 1 week, 3 months and 9 months after you have completed your course of counselling (the follow-up interviews may be face-to-face, or by telephone).

In addition, we will ask you to:

- complete a brief questionnaire immediately before each counselling session
- agree to audio recording of counselling sessions.

If you wish to take part in the overall study, but do not feel like taking part in any of these research tasks on any particular occasion, you are free to decline, without giving a reason. We appreciate that there are several questionnaires to be completed by you in this research. You are free to ignore any questions that you do not wish to answer. We will ask you on a regular basis to check if you are comfortable with this, and willing to continue as the research proceeds.

We will pay your travel expenses for visits to the counselling centre, to take part in the follow-up research interviews.

What do you have to do?

If you agree to take part in the study, we expect you to give up some of your time to complete questionnaires, and be interviewed. It is important that you continue to contribute to the study even after you have finished counselling, so we can get a full understanding of the effect of counselling over the follow-up period.

What is the procedure being tested?

The counselling you will receive is short-term counselling (up to 12 sessions of individual therapy), using an approach that emphasises the

development of a relationship of trust between client and counsellor as a means of enabling the person to find and apply their own resources and solutions to resolve problems in living, and enhance well-being.

What are the alternative treatments that are available?

There is evidence that problems that can be helped through individual counselling can also be effectively managed by cognitive-behaviour therapy from a clinical psychologist, group psychotherapy, drug treatments, participation in a self-help group, or working through a self-help book or manual. Each of these interventions has its own distinctive advantages and disadvantages. Your GP, or the person who carries out your initial interview at TCC, will be happy to discuss these alternative sources of help with you.

What are the side effects of counselling, and risks of taking part in this study?

There is a possibility that you may find counselling emotionally upsetting at times, and that you may find yourself reviewing aspects of your current life situation. The questionnaires and interviews that you will be asked to complete are designed to complement your counselling, and do not constitute a risk. If the data collected in the research indicates that you may have a mental health problem that requires additional treatment, we will let you know, and advise you to consult your GP. If the data indicates that you are at risk of harming yourself or another person, we will discuss this with you, and will ask your GP to get in touch with you.

What are the possible benefits of taking part?

We cannot promise that the study will help you personally, but the information we receive may help improve the quality of counselling services provided to GP patients in future. In other studies of this type, some participants have found that completing questionnaires and interviews has been beneficial in helping them to focus on the problems they wish to discuss with their counsellor.

What happens when the research study stops?

Throughout the study, you are free to consult your GP about any other help you may need. Once you have completed your involvement in the

research study, you will be eligible to receive further counselling from TCC, if you need it. At the end of the research study, if you are interested in learning about the results of the research, you are welcome to contact TCC to receive a copy of our report.

What if there is a problem?

Any complaint about the way you have been dealt with during the study will be addressed. Detailed information on what to do if there is a problem is given in the TCC Complaints Procedure.

What will happen if I don't want to carry on with the study?

You are free to withdraw from the study if you wish to do so. If you choose to withdraw from completing research questionnaires and interviews, you will be eligible to continue to receive counselling, or any other treatment recommended by your GP. If you withdraw from the research, we write to you to ask whether: (a) you are willing for us to use the research information collected up to the date of your withdrawal, or (b) you would prefer that we destroy all the information we have collected on your counselling. If you do not reply to our letter, we will implement option (b) – destroying all information.

You may also choose, at any stage, to stop attending counselling, but to continue to be followed-up for research purposes.

Will my taking part in the study be kept confidential?

Yes. All information about your participation in the study will be kept confidential. You will be given a code number, and all information about you that is stored will be identifiable only by that anonymous code. All information that you provide will be stored in a locked filing cabinet or secure electronic database, to which only the researchers will have access. Representatives of the NHS Tayside Research Ethics Committee have the right to look at the data to ensure that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and nothing that could reveal your identity will be disclosed outside the research site. Procedures for handling, processing, storage and destruction of data are compliant with the Data Protection Act 1998.

The Tayside Committee on Medical Research Ethics, which has the responsibility for scrutinising all proposals for medical research on humans in Tayside, has examined the proposal and has raised no objections from the point of view of medical ethics. It is a requirement that your records in this research, together with any relevant medical records, be made available for scrutiny by monitors from the University of Abertay and NHS Tayside, whose role is to check that research is properly conducted and the interests of those taking part are adequately protected.

All research information will be retained for 5 years following the end of study, to allow the TCC research team to complete its analyses of the data. Your information then will be disposed of securely, unless you provide us with written permission to use it for further research purposes. If this occurs, you will be invited to complete a new informed consent form.

Your GP will be informed that you have agreed to take part in this study. Your GP will not receive any other information arising from your participation in the research.

With your permission, we may wish to provide material from the research records, in a fully anonymous way, to an international archive. This archive will only be accessed by approved researchers, and will be used for future training and research purposes.

What if relevant new information becomes available, about the treatment I am receiving?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your GP will tell you about it, and discuss whether you want to or should continue in the study. If you decide not to carry on, your GP will make arrangements for your care to continue. If you decide to remain in the study you will be asked to sign an updated consent form. If the study is stopped for any other reason, you will be told why and your continuing care will be arranged.

What if there is a problem?

If you have concern about any aspect of the study, you should speak with the researchers, who will do their best to answer your questions (tel: XXXX). If you remain unhappy and wish to complain formally, you can do this through the TCC Complaints Procedure (copy attached, or available at the TCC reception desk). In the event that something goes wrong and you are harmed during this research study there are no special compensation arrangements. If you are harmed and this is due to someone's negligence you may have grounds for a legal action against

either the individual counsellor or the sponsor of the research (University of Abertay Dundee), but you may have to pay your own legal costs. Further information is available in the TCC Complaints Procedure.

What will happen to the results of the research study?

The results of the study will be published in scientific journals and at scientific conferences. Copies of publications can be requested, without charge, from TCC. You will not be identified in any report or publication unless you have specifically consented to release such information.

The information collected during the study will be analysed in two ways. First, trends and themes emerging from the whole sample of people taking part in the research will be examined. Second, case studies of individual users of counselling will be compiled. If your individual information is being considered for inclusion in a case study, you will be asked for further consent, once you have completed counselling.

Who is organising and funding the research?

This research is funded mainly by XXXX.

Who has reviewed this study?

The plan for this study was given a favourable ethical opinion by the local NHS Research Ethics Committee (tel: XXXX) and the Research Ethics Committee of the School of Social and Health Sciences, University of Abertay Dundee (Chair: XXXX, tel: XXXX).

Contact details

For any further information about the study, please contact:

John McLeod

Director, Tayside Centre for Counselling

(address and phone number added)

Thank you for taking the time to read this Information Sheet