Oracle App: Field-test of a dynamic outcome feedback system for psychological therapy

We would like to invite you to participate in a study investigating the acceptability of dynamic outcome feedback as part of routine psychological care. The study is sponsored by the RDASH NHS trust, working in collaboration with the University of Sheffield. The study is part of a wider international collaboration to develop outcome feedback technology. The project has been ethically approved by the NHS Research Ethics Committee (IRAS project ID: 294725). This leaflet will explain the study and clarify what you can expect if you decide to participate.

Background and purpose

Research suggests that outcome feedback (OF) can help to improve the effectiveness of psychological therapy. OF involves monitoring patients' progress using self-reported symptom questionnaires. Questionnaire responses are entered into a computer system that uses outcome prediction methods which help therapists to detect cases at risk of poor outcomes. OF systems help therapists to 'troubleshoot' rapidly, potentially reducing the chances of dropout and further deterioration.

This study aims to recruit a cohort of therapists to field test a novel dynamic outcome feedback system as part of their routine therapy contacts and clinical supervision meetings. We will gather data from therapists and a sample of patients to learn about their experiences and views about the usability and acceptability of the technology. Use of the Oracle App will not affect the care patients receive or change any of the clinical decisions therapists take in relation to their care.

How exactly does outcome feedback work?

1. The Oracle system can be accessed using web browsers. Therapists are provided with a password protected account that enables them to register their patients onto the system using pseudonymised ID numbers.

2. Individual patients' progress on the core IAPT outcome measures will be plotted onto charts to show symptom changes from session-to-session. The charts will compare patients current progress in therapy to an expected treatment response and provide a personalised probability of recovery after therapy. Oracle will learn from the patients' prior progress in therapy and update predictions as treatment progresses.

3. The system will detect and flag up cases as being 'on track' (OT) or 'not on track' (NOT). Therefore, you will be regularly 'alerted' to cases that are not progressing as expected or who are at risk of a poor outcome.

4. When therapists are 'alerted' to patients who are at risk of poor progress, they are encouraged to discuss their concerns with their patients and to raise this in clinical supervision meetings. As part of the study, we will offer therapists training and ideas about how they could troubleshoot and improve outcomes for high risk cases.

Who will be eligible to participate?

- Any qualified therapist delivering (Step 2 or Step 3) evidence based psychological interventions within the RDASH IAPT Partnership.

Exclusion criteria: Staff who are currently in training that has very specific supervision requirements; staff who are unable to participate in the study for at least 6 months.

How will the study work?

- Participating therapists will attend a half training day on *Thursday 21st October* (PM), which will explain the application of outcome feedback and will include a workshop on troubleshooting and clinical skills. After the training day, they will be registered onto the system, assigned an ID code and given access to the Oracle App.
- Therapists will be asked to use the Oracle App in their clinical practice with verbally consenting patients who start treatment over a 6 month period. A verbal consent script will be provided to support therapists in obtaining consent and consent will need to be documented in the patients clinical notes.
- Two months into the field test, Clinical Studies Officer's in the RDASH research team will then undertake a semi-structured virtual interview with participating therapists, for about an hour, to learn about their experiences of using the Oracle App. Questions will relate to therapists views about the usability and acceptability of the App.
- A sample of participating therapists' patients will also be invited to take part in virtual interviews, to learn about their experiences and views about the outcome feedback technology.
- At the end of the study we will invite therapists to a half day workshop in which we will share findings and consult with therapists on recommendations.

What data will be collected for the study?

- We will ask you to provide some brief demographic information and answer a short survey about your therapeutic training, professional development, and supervision. This data will be anonymous and used for the purpose of providing group-level summaries of the sample.
- All interview data will be video recorded and auto-transcribed using Microsoft Teams video conferencing and transcription software. Participants can keep the camera turned off if they prefer. After the transcriptions have been verified, they will be pseudo-anonymised by the RDASH research team and the recordings will be deleted. This means people who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.
- All information you provide during the interview will be kept confidential. The only situation where *confidentiality may be broken* would be if during the interview you disclose any issues that may impact on your safety or the safety of others.
- When the study finishes, your name or other identifiable information will be removed from the database and the study results will be worked out using anonymous data.
- The final anonymised dataset will be passed to the collaborating research team at the University of Sheffield for analysis and will be stored in a secure University network drive, only accessible to members of the collaborating research team. Anonymised research data will be stored for a minimum of 5 years.

What happens at the end of the study?

All information will be strictly anonymised, securely stored and gathered into a final study database. No personal data will be included. The data will be qualitatively analysed by the research team. We hope to publish a paper in a scientific journal to share our findings with staff, researchers and participants. We will also provide you with a brief summary of our findings when the study concludes. Our learning and your contributions will help us to inform the future development of outcome feedback tools for IAPT services.

Does the study have ethical approval?

This study has received ethical approval by the Wales Research Ethics Committee and was approved by the NHS Health Research Authority.

Your rights as a participant

- You can expect to have an opportunity to clarify any questions or discuss any concerns with a member of the research team, before you consent to participate, and at any time during the course of the study.
- You will have opportunity to interact with the research team and to express your views about the study and the use of outcome feedback: at the training and consultation events and through confidential qualitative interviews.
- You are entitled to withdraw your consent to take part in the study at any point.
- If you decide to withdraw from the study, we will treat any data that you provided entirely anonymously for the purpose of data analysis, unless you ask us to remove your data from the study.
- You can expect to be informed about the study findings once these have been written.
- If for any reason wish to discuss the study or make a complaint you can contact the research team, or you may contact the Chief Investigator directly (see details at the end of the document).
- Alternatively, you can also contact the Information Commissioner if you have a complaint about processing of your personal data: The Office of the Information Commissioner, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF. Phone: 0303 123 1113 or 01625 545 745

Legal statement under the General Data Protection Regulation (GDPR)

How will we use information about you?
RDaSH will need to use information from you for this research project. This information will include your name and email. This information will be used strictly for the purpose of contacting you to arrange a virtual interview. The information that is collected as part of your participation in the study will be fully anonymised, and linked to a participant ID number instead of your name or email. RDaSH will keep all information about you safe and secure in a password protected network drive, which is only accessible to a restricted number of research team members who are in charge of data collection. Once the team has finished the study, we will keep fully anonymous data so we can work out the results. This final anonymised dataset will be shared with our collaborating researchers at the University of Sheffield for analysis. We will write our reports in a way that nobody will know that you took part in the study. The anonymous data you provide will possibly be used in future studies too, and by other authorised researchers. If you agree to take part in this study, you will have the option to be informed of the results via email at the end of the study using contact details you provide.

What are your choices about how your information is used?
You can stop being part of the study at any time, without giving a reason, but we will keep anonymized information that you contribute to the study. The team will use this information to carry out analysis of data, and to produce results and recommendations for research. This means that we won't be able to let you change the data we hold about you, after it has been collected and fully anonymised.

Where can you find out more about how your information is used?
You can find out more about how RDaSH will use your information: GDPR Compliance
You can also request further information from the research team or email the Trust Data Protection Officer at rdash.dpo@nhs.net

What do I have to do if I want to take part?
Please use the link below to access the online consent form. You will be asked to provide contact details and confirm your consent to participate.

https://sheffieldpsychology.eu.qualtrics.com/jfe/form/SV_3TOYqaLK3is5ZsO

Contact details for further info or questions:

Chief Investigator: Dr Jaime Delgadillo, email - jaime.delgadillo@nhs.net
Grounded Research Team, Almond Tree Court, Tickhill Road Hospital, Balby, Doncaster, DN4 8QP

Principal Investigator: Dr Melanie Simmonds-Buckley, email – m.simmonds-buckley@sheffield.ac.uk, Tel – 0114 222 6630. Postal address – Clinical Psychology Unit, Department of Psychology, Floor F, Cathedral Court, 1 Vicar Lane, University of Sheffield, S1 2LT.

Collaborators: Research collaborators outside of RDASH NHS Trust will support the analysis of anonymous data only.

AiOracle Collaborating Research Team:
Dr Claire Bone, Clinical Psychology Unit, University of Sheffield, UK
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David Sandford, Lancashire and South Cumbria NHS Foundation Trust, UK
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Thank you for taking time to consider participating in this research.