A web-based, peer-supported self-management intervention to reduce distress in relatives of people with psychosis or bipolar disorder: the REACT RCT

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Disclaimer: This report contains transcripts of interviews conducted in the course of the research and contains language that may offend some readers.

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Scientific summary

The REACT RCT

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Scientific summary

Background

Relatives supporting people with a severe mental health problem, such as psychosis or bipolar disorder, face many challenges and report high levels of distress. Psychoeducation and emotional support through peer interactions are effective, beneficial and recommended by the National Institute for Health and Care Excellence. However, evidence shows that many relatives are unable to access these services. The Relatives' Education And Coping Toolkit (REACT) was an online, supported self-management package designed to improve availability and access to support for relatives. It included a comprehensive online resource directory.

Objectives

The aim of the trial was to determine the clinical effectiveness and cost-effectiveness of REACT with the resource directory and treatment as usual, compared with only the resource directory and treatment as usual. This was the first definitive randomised controlled trial to test an online digital health intervention for relatives of people with severe mental health problems.

The objectives were to determine the:

- impact of REACT on relatives' distress
- impact of REACT on relatives' well-being and support
- impact of REACT on hypothesised mediators of change including relatives' beliefs, perceived coping and amount of use of REACT
- costs associated with delivery and maintenance of REACT
- incremental cost-effectiveness ratio of REACT.

The primary hypothesis was that there would be a significant difference ($p < 0.05$) between the two arms of the trial in levels of relatives' distress at the 24-week follow-up.

Methods

The design was an online, single-blinded, two-arm randomised controlled trial.

Eligible participants were relatives or close friends engaged in caring for a person with psychosis or bipolar disorder. Inclusion criteria were as follows: aged $\geq$ 16 years, living in the UK, currently experiencing high levels of distress as a result of their caring role (assessed using a single item from the General Health Questionnaire-28 items, 'Being strung-up and nervous all the time', which required a response of 'rather more than usual' or 'much more than usual' for eligibility), actively seeking help, access to an internet-enabled computer and sufficient command of English to use REACT (which was available only in English). Only one relative per family could take part, and relatives living in any of six geographical areas taking part in a parallel implementation study [the IMPlementation of A Relatives' Toolkit (IMPART) study] of the same intervention were excluded by postcode.

REACT included 12 psychoeducation modules addressing key questions identified by relatives, peer support through a moderated group forum, a confidential direct messaging service and the resource directory of contact details for national organisations offering relevant support.

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Relatives with lived experience of supporting someone with a mental health problem were trained to moderate the forum, respond to confidential messages from users and guide users to relevant parts of the toolkit and/or other resources as appropriate. The toolkit was hosted by one NHS mental health trust in England, but was available to relatives across the UK.

The comparator intervention was access to the same resource directory. All trial participants received treatment as usual.

Participants were recruited through mental health services, charities, media, social media and online advertisements. After providing informed consent and baseline data, eligible participants were randomised, using a 1 : 1 ratio, to 'REACT (including the resource directory) plus treatment as usual' or to 'the resource directory plus treatment as usual', using web-based variable block randomisation, in which the unit of randomisation was the relative. Following randomisation, participants received an e-mail telling them which arm of the trial they had been allocated to. The e-mail included a link to the REACT website, and their username and password. All accounts were set up on the same website, but those in the resource directory-only arm had access only to the directory. All participants were aware that the resource directory was one component of the REACT intervention; therefore, they were likely to have perceived REACT as the 'intervention of interest' and the resource directory as the comparator.

All outcomes were validated self-report measures, collected online using a closed system available only to participants with an account on the REACT website. We gave participants shopping vouchers at each time point as an incentive to complete the follow-up measures.

The primary outcome was relatives' distress at 24 weeks, assessed using an online version of the General Health Questionnaire-28 items, with Likert scoring. Based on our previous feasibility trial, and accounting for design changes and dropout, we aimed to recruit 666 relatives to provide 90% power to reject the null hypothesis ($p < 0.05$), assuming an estimated mean difference of 5.0 units on the General Health Questionnaire-28 items (standard deviation 16.6 units) and 30% dropout by 24 weeks.

Secondary outcomes included the relatives' well-being and experience of support, assessed online using the Carer Well-being and Support questionnaire at 12 and 24 weeks, and distress (measured using the General Health Questionnaire-28 items) at 12 weeks' follow-up. Illness perceptions (assessed using a modified version of the Brief Illness Perception Questionnaire) and coping (assessed using the Brief Coping Orientation to Problems Experienced) were hypothesised mediators of the intervention effect. The costs of health and personal social care use were assessed using a modified version of the Client Service Receipt Inventory, and quality of life was assessed using the EuroQol-5 Dimensions, five-level version, at baseline and at 12 and 24 weeks.

Mean scores were compared between arms using analysis of covariance, adjusting for baseline scores. A joint modelling approach was used to assess differences in longitudinal outcomes between the randomised arms, adjusted for missingness (at 12-week or 24-week follow-ups). Multivariate analysis of covariance was used for exploratory analyses of the impact of intervention arm on each subscale of the mediator measures, while taking into account correlation between the subscales. Instrumental variable regression was used to estimate the impact of intervention use on outcome. Further exploratory analyses assessed the impact of reading but not posting (known as 'lurking') on the REACT forum.

Participants' experiences of using REACT were explored quantitatively (all participants were in the REACT arm) and qualitatively (purposive sample of 24 participants in the REACT arm). Adverse events were closely monitored. A full statistical analysis plan was published prior to any data analysis.

Results

The total number of visits to the REACT trial page during the trial was 51,832. The total number of visits to the registration page was 4348. Of the 3287 people who completed the eligibility screening, 1416 failed on at least one of the eligibility criteria, with 1146 (81%) of these failing to report higher than usual levels of distress. Of the 1528 (46%) who subsequently provided consent for the study, 807 completed baseline measures and 800 (52% of those consenting) were randomised. Of these, 424 (53%) were recruited through primarily online strategies [Facebook (Facebook, Inc., Menlo Park, CA, USA) advertising being the most successful], and 376 (47%) were recruited through primarily offline strategies (mainly via mental health services).

Participants were typically middle-aged (40–60 years: $n = 422$, 53%), white British ($n = 727$, 91%), female ($n = 648$, 81%), mothers ($n = 387$, 48%), highly educated (university level: $n = 437$, 55%) and supporting an adult aged < 35 years ($n = 485$, 61%). More than half of participants ($n = 462$, 58%) were supporting someone with bipolar disorder. Most were supporting only one person, but 209 (26%) reported supporting two or more people, and the majority ($n = 457$, 57%) also had other dependants. A total of 485 (61%) were married or in a civil partnership. The majority of relatives were in full-time, part-time or voluntary work ($n = 512$, 64%), but 66 (8.5%) reported being unable to work specifically because of their caring responsibilities. The vast majority had home internet access ($n = 795$, 99%). Retention was 74% at 12 weeks and 75% at 24 weeks.

Taking into account the full costs of development and delivery, REACT cost £142.95 per person, and the resource directory cost only £0.84 per person. Most of these costs were development; ongoing delivery would cost £62.27 for REACT and £0.43 for the resource directory.

The median time spent on REACT in the REACT arm was 50.8 minutes (interquartile range 12.4–172.1 minutes, range 0.1–4505.5 minutes). The median time spent on the resource directory was 0.5 minutes (interquartile range 0–1.6 minutes, range 0–42.9 minutes). Both online interventions (REACT and the resource directory) were accessed considerably more outside the working week (09.00–17.00, Monday–Friday, excluding public holidays) than during working hours, suggesting a need for online interventions to be available 24 hours a day. The most popular module (with most people visiting at least once) was the online forum.

Relatives had high levels of distress (measured using the General Health Questionnaire-28 items) at baseline (mean score 40.2, standard deviation 14.3), which decreased in both arms by the 24-week follow-up (overall mean score 30.5, standard deviation 15.6), but there was no significant difference between the two arms (−1.39, 95% confidence interval −3.60 to 0.83; $p = 0.22$). At 12 weeks' follow-up, the General Health Questionnaire-28 items scores were lower in the REACT arm than in the resource directory arm (−2.08, 95% confidence interval −4.14 to −0.03); although statistically significant ($p = 0.027$), this was likely to be of limited clinical significance. After accounting for missing data in a longitudinal model, there was no significant difference between REACT and resource directory arms over the 24-week follow-up period (−0.56, 95% confidence interval −2.34 to 1.22; $p = 0.51$). Participants in the REACT arm who dropped out were, on average, 0.33 General Health Questionnaire-28 items units (95% confidence interval −0.27 to 0.93; $p = 0.279$) more distressed than those who remained. Being male, single and unemployed (or in unpaid work) were all associated with greater levels of distress.

Carer well-being and support both increased significantly over time in both arms. There were no significant differences between arms in well-being at either 12 weeks (1.53, 95% confidence interval −2.21 to 5.27; $p = 0.42$) or 24 weeks (2.39, 95% confidence interval −1.76 to 6.54; $p = 0.26$). Relatives in the REACT arm reported higher levels of support at 12 weeks (2.50, 95% confidence interval 0.87 to 4.12; $p < 0.0001$) and at 24 weeks (1.65, 95% confidence interval 0.04 to 3.27; $p = 0.045$). However, after accounting for missing data in a longitudinal model, the mean difference (1.51, 95% confidence interval −0.005 to 3.01) was no longer statistically significant ($p = 0.051$) and was likely to be of limited clinical significance.

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The within-trial health economic analysis of NHS, health and Personal Social Services outcomes found REACT to have higher costs (of £286.77, 95% confidence interval −£858.81 to £1432.36; $p = 0.624$), slightly better General Health Questionnaire-28 items scores (incremental General Health Questionnaire-28 items scores adjusted for baseline General Health Questionnaire-28 items score, age and gender −1.152, 95% confidence interval −3.370 to 1.065) and slightly lower quality-adjusted life-year gains (incremental quality-adjusted life-years adjusted for baseline EuroQol-5 Dimensions, five-level version, index score; age; and gender −0.0024, 95% confidence interval −0.0088 to 0.0039) than the resource directory only, but none of these differences was statistically significant.

Illness perceptions and perceived coping improved over time. However, neither had a significant mediation effect on outcome. There was no evidence of a causal association between amount of use of REACT and impact on outcomes. The REACT forum users were estimated to have lower General Health Questionnaire-28 items scores at 24 weeks than non-users (−2.0, 95% confidence interval −5.9 to 1.9), who had similar outcomes to people reading but not posting ('lurkers') (−0.1, 95% confidence interval −3.2 to 2.9); however, there was no evidence of a significant difference ($p = 0.59$).

The intervention appeared highly acceptable. Participants reported finding REACT a safe and confidential environment (96%), feeling supported by the REACT arm (89%) and by the REACT supporters (86%). There were no serious adverse events (i.e. immediate and serious risk to life or to child welfare). Qualitative feedback was extremely positive. REACT was particularly valued by relatives for being comprehensive, relevant, easy to access, private and anonymous. The proactive support from the REACT supporters was appreciated, as was the opportunity to learn, through a variety of different media (e.g. text, video, forum), how best to support someone with a mental health problem. However, a consistent message was that REACT would be most useful to relatives early in the recovery journey, when they were likely to seek information and strategies. Some relatives found seeking help for their own needs difficult, and most relatives found prioritising time to use the REACT difficult. The advantage of online interventions is that they are conveniently accessible at any time, but the challenge is to make time to use them.

Conclusions

Relatives felt safe and well supported using REACT, which might facilitate better engagement with other aspects of the service. Key developments should include the following: redesigning the content and presentation using feedback from participants; making the technology more interactive and user friendly; increasing the role of the REACT supporters to include support to use the modules; specifying recommended levels of use; and offering REACT to relatives earlier in the recovery journey, alongside other components of care, particularly for those with high levels of distress.

Recommendations for further research

- Given the apparent unmet need and high acceptability of REACT, further work is needed to make the content of REACT more effective.
- Psychoeducation and support are important and valued by relatives, but distress (measured by the General Health Questionnaire-28 items) may not be the most appropriate outcome for evaluating their effectiveness. Understanding more about a chronic health problem for which there is no immediate cure is important, but is unlikely to reduce distress without additional therapeutic input. Therefore, the effectiveness of psychoeducation interventions may be better tested against alternative outcomes, such as supporting relatives to feel more knowledgeable, more empowered, better able to cope and more engaged with services, rather than on reducing distress.
- Research is needed to understand how to increase engagement and use of REACT (and other digital health interventions) to maximise their potential to improve outcomes.

- Research is needed to understand how to improve uptake and reach of REACT (and other digital health interventions) by groups that currently show low levels of use of mental health and support services, including ethnic minority groups and men.
- The impact of psychoeducation interventions for relatives on service user outcomes needs to be tested.
- Randomised controlled trials can be delivered online at lower cost. However, this methodology presents new challenges in keeping participants engaged throughout long-term follow-ups, and in managing high-quality patient and public involvement. Both require further research.

Trial registration

This trial is registered as ISRCTN72019945.

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This report

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