Feasibility of Relatives’ Education and Coping Toolkit - REACT

Feasibility of a supported self-management intervention for relatives of people with recent onset psychosis: REACT study.

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Abstract

**Background** Relatives of people with psychosis experience high levels of distress and require support. Family interventions have been shown to be effective in improving outcome but are difficult to access and not suitable for all relatives.

**Aims** This study assesses the feasibility and effectiveness of a supported self-management package for relatives of people with recent onset psychosis.

**Method** A randomised controlled trial (n = 103) comparing treatment as usual in Early Intervention Services with treatment as usual plus the REACT intervention.

**Results** Compared to TAU only, those receiving the additional REACT intervention showed reduced distress and increased perceived support and perceived ability to cope at 6 months follow-up.

**Conclusions** REACT is a feasible and potentially effective intervention to improve outcome for relatives. A larger trial is needed to reliably assess the clinical and cost effectiveness of REACT, and its impact on longer term outcomes.

*(Words = 149)*

**Declarations of interest**

None

Trial identifier: ISRCTN69299093
Introduction

First episode psychosis commonly occurs in adolescence when most people live with their parents. It is associated with high levels of distress in relatives [1, 2]; evident from a very early stage of illness [3, 4]. The UK government has expressed a strong commitment to supporting relatives [5], not least because the care they give saves the NHS a vast amount of money each year [6]. Family Interventions have been shown to be effective in improving outcome for people with schizophrenia [7] and are recommended by the National Institute for Health and Clinical Excellence (NICE) [8]. A recent meta-analysis suggests positive benefits from family interventions in first episode populations [9], though this approach may not always be suitable at this stage [10]. The impact of family interventions on relatives’ outcomes, such as distress and wellbeing is less clear as often these are either not assessed, or only as secondary outcomes [11]. Implementation of family interventions in real world clinical settings is poor. Significant barriers include lack of engagement with families, lack of confidence and training amongst clinicians, high caseloads, and an individualised model of care [12]. Consistent with government policy on the management of long-term conditions [13] is the option of developing supported self-management approaches which provide relatives with the knowledge and skills they need at a pace and intensity they can control. Such approaches have the potential to vastly improve access, are inherently empowering in their ethos and are relatively easy and cheap to deliver. Although self-management approaches are being developed across a wide range of physical health conditions [14], less progress has been made in mental health, with the notable exception of eating disorders ([15, 16]). The Relatives Education and Coping Toolkit (REACT) study is the first study to evaluate the feasibility and effectiveness of a supported self-management intervention for relatives...
of people experiencing recent onset psychosis. The main aims are to determine (i) acceptability of the intervention; (ii) preference for type of support; (iii) rates of recruitment and retention; (iv) likely effect size on a range of outcomes for relatives.

**Method**

This study was approved by a local National Health Service (NHS) Ethics Committee (REC ref: 08/H1001/147) and three participating NHS Trusts in the North West of England.

**Trial design**

This is a stratified randomised controlled trial in which participants are allocated to receive either treatment as usual (TAU) or TAU plus the REACT intervention. Following baseline assessments, independent randomisation was done by a UK Clinical Trials Unit using permuted blocks within NHS Trust with randomly varying block sizes. A detailed study protocol is published elsewhere [17].

**Participants**

Participants were relatives, partners or close friends of people experiencing psychosis who were currently being supported by the Early Intervention Services (EIS) within a participating NHS Trust. These teams support young people experiencing psychotic symptoms between the ages of 14 and 35 for a period of up to three years [18]. Only relatives in direct contact with the EIS were invited to take part. Only one relative per family (the self-identified main carer) took part in the study but they were encouraged to share the intervention with other close family members. Additional inclusion criteria were that first contact with EIS was within the last 24 months and
that participants were aged over 18 and had sufficient understanding of written and spoken English (Translations and interpreters were not routinely available). All participants gave written informed consent. All service users were informed about the study but were not required to consent as they were not participants.

Procedure

Assessments were carried out in face-to-face interviews in the relatives’ home, NHS or University premises at baseline and 6 months follow-up by a Research Assistant (RA) who was blind to allocation. Relatives in both arms of the study were invited to take part in qualitative interviews about the difficulties they faced in supporting someone with psychosis, and how they coped with these. Those in the REACT arm also gave feedback on the intervention. These data will be reported elsewhere.

REACT Intervention

The development of the REACT intervention was informed by (i) a systematic review of interventions reporting on outcomes for relatives of people with psychosis [11]; (ii) a series of focus groups with relatives [19]; (iii) clinical and personal expertise within the research team (consisting of relatives, clinicians, and academics); and (iv) extensive feedback from service users and relatives throughout the process. The toolkit is comprehensive and modular in format so that the content is divided into thirteen manageable sections which can be used flexibly depending on the individual needs of the relative. These include: Introduction to REACT; What is Psychosis?; Managing Positive Symptoms; Managing Negative Symptoms; Dealing with Crises; Dealing with Difficult Behaviour; Managing Stress – Thinking Differently; Managing Stress – Doing Things Differently; Understanding Mental Health Services; Treatment
Options; The Future; Resource Directory; Jargon Terms. Modules range between eleven and twenty-three A5 pages, though the Resource Directory is considerably longer at forty-three pages. Extensive use is made of signposting to other resources, which requires the toolkit to be regularly updated. Although the information is about psychosis in general, the toolkit is designed to help relatives to make this information specific to their family by identifying key questions they may need to ask to get the information they require. Case examples are used to aid illustration. The content of the toolkit reflects the key ingredients in existing evidence based family interventions.

All participants were given a printed version of the toolkit and offered an online version.

Each participant was supported in the use of the toolkit by an EIS support worker. These workers are well placed to support this self-management approach as it does not require highly trained health professionals, but does require availability and flexibility. They are also relatively inexpensive, lowering cost barriers to further dissemination. Supporters attended four days of training spaced over three months, followed by monthly group supervision for the duration of the project. The EIS in the three NHS Trusts were organised in a Hub and Spoke model and further divided into smaller teams to cover the wide geographical areas. One Trust identified a support worker to be trained in each of two teams and two supporters in the third team.

Another Trust allocated one supporter to work across all three of its teams. The final Trust operated as a single team and had one supporter. In total seven teams took part and six supporters were trained.

All relatives were offered an initial face to face session in which they were introduced to the toolkit and arrangements for support agreed. Support was offered by email or telephone (relatives’ preference) for a maximum of one hour per week over six
months. To ensure communication was maintained, supporters were asked to contact relatives monthly as a minimum if the relatives did not respond to appointments or initiate contact.

Support was targeted at helping relatives to identify the key difficulties they faced and guiding them to find the most relevant information and strategies in the toolkit. Discussion then focussed on making these general principles as directly relevant as possible to each individual participant, and on helping relatives to try out new strategies and reflect on the outcomes of this. The toolkit and the support was designed to make the intervention “enactive” rather than “symbolic” i.e. it encourages relatives to actively practice new skills, rather than just providing information [20].

**Treatment As Usual (TAU)**

TAU as outlined by the operational policies for all participating NHS Trusts included:

- A carers’ assessment and ongoing assessment of need for relatives;
- Development of a shared formulation of individual and family difficulties;
- Emotional support;
- Information about mental health and the mental health system;
- Practical support – finances, accommodation etc;
- Links to other support / services;
- Early crisis intervention;
- Relapse prevention;
- Stress management;
- Referral to structured family intervention where needed. Two of the Trusts also ran monthly Family and Friends peer support groups facilitated by a health professional. Participants in TAU were asked to complete a checklist to indicate to what extent they felt they had received each of these elements. This was used to describe the TAU intervention.

**Measures**
This paper reports on the impact of the REACT intervention on the main outcome measures, selected for being valid and reliable measures of distress and wellbeing. The General Health Questionnaire GHQ-28 [21] was used to assess distress. This is a widely used measure and allowed comparison with other studies in this area. Participants indicate whether their current state differs from their usual state, thereby assessing recent changes in distress as opposed to long-term traits or illnesses. Scoring using the likert scale method was used for the analysis. We also report on clinical caseness defined as scoring 6+ using the standard scoring (0,0,1,1) [21]. The Experience of Caregiving Inventory [22] measures the experience of caring for a relative with a serious mental illness. Totals for the negative and positive subscales were used. The Carer Well-Being and Support Questionnaire [23] is designed to cover all aspects of the carer’s experience of caring for someone with a serious mental health problem including relationships, roles, financial concerns, physical/emotional health, stigma, worries about safety, their satisfaction with support offered and ease of obtaining information. The Family Questionnaire (FQ) [24] was used to assess relatives’ concern and perceived ability to cope. The FQ presents participants with a range of symptoms of mental illness that have the potential to pose a problem in family life. It assesses the extent to which each of these symptoms cause the relative concern and how well the relative is able to cope with their concerns. The Herth Hope Index [25] consists of 12 self report items designed to assess hope in adults in clinical settings.

Quality Assurance
All baseline assessments were carried out by two RAs who were trained in administering and scoring all measures. Training included role-play practice interviews with relatives and weekly supervision to discuss clinical and scoring issues as they arose. Following randomisation, one of the RAs was made aware of allocation and carried out all communication with participants and associated health professionals and in-depth qualitative interviews with participants during the process of the study. She contacted all participants prior to their follow-up appointment to emphasise the importance of not revealing allocation to the second RA at the follow-up interview. The second RA remained blind to allocation, was housed in a separate office, had no direct contact with participants or health professionals outside the follow-up interview and no access to databases that contained participant allocation details.

**Statistical Analysis**

Analyses were conducted on an intention to treat basis. A per protocol analysis was not considered appropriate as we deliberately did not specify a protocol for how much time participants should spend reading the toolkit, or how much support they should receive as this should vary according to need. All participants received the toolkit and offer of support. The two-sided significance level was set at alpha = .05. Where data for an entire measure was missing (i.e. non-response on all items), this was regarded as a missing value. If less than 10% of items on a single measure were missing, these missing items were imputed by the average of the non-missing items for that participant (i.e. ‘prorated’).

Comparison between those receiving TAU and those receiving TAU+REACT on each of the outcomes was carried out using ANCOVA controlling for baseline scores.
and clinical EIS team. Missing data will not invalidate the ANCOVA method as long as the missing data are occurring at random, conditional on the covariates in the model (MAR, using the terminology of Little & Rubin, [26]). Regression coefficients with 95% confidence intervals are reported along with robust standard errors and p value (using the robust option in Stata’s regress command). Robust standard errors were used so that the results were not dependent on assumptions of normality. Chi-squared analyses were used to compare the numbers of relatives moving between the categories of “caseness” and “noncaseness” in the two arms to give a more clinical interpretation of the findings.

Results

Participants- recruitment and retention

Figure 1 here

Figure 1: CONSORT diagram showing flow of participants through the study

One hundred and forty four relatives were initially referred into the study. Twenty-one subsequently declined to take part (15 gave no reason, 3 felt they didn’t have time, 1 disagreed with the diagnosis their relative had been given, and 2 felt they already had enough support). Eight were subsequently identified as ineligible (4 had been in the service too long, 1 was unable to understand English sufficiently, 1 was blind, 1 was a service user and 1 was not in the participating EIS). Twelve were not contactable.

One hundred and three relatives were randomised. The majority were female (85:18 F:M), white British (97 (94%)) and the mother of the service users (76 (74%)). Forty-six (45%) were unemployed or retired, 34 (33%) were in full time work, and 22
(21%) in part time work. Eighty-six (78%) were aware of a diagnosis having been given, most common being psychosis (43 (50%)), schizophrenia (7 (7%)) and bipolar disorder (4 (4%)). The majority of relatives lived with the service user all of the time (75 (73%)).

Relatives’ perception of how long the service user had experienced mental health problems was skewed with a median of 36 months (range 3–240) and their perceived time since diagnosis had a median of 9 months (range 0-144). Self reported length of time in the EIS team was reported as median of 9.5 months (range 2–34.5 months).

**Participants’ baseline scores**

Baseline scores are shown in Table 1

*Insert Table 1 here*

**Table 1. ANCOVA comparing follow-up scores controlling for baseline and team**

Levels of distress were generally higher than those reported in previous samples of relatives of people in early psychosis [27, 28]. Sixty-seven (65%) relatives scored above the threshold for clinical caseness at baseline, suggesting this was a highly distressed group. There was no significant difference between those retained at follow-up and those lost to follow-up on the GHQ at baseline.

Where available, scores on the other measures were also compared to previous studies of comparable samples. Relatives in this study reported equivalent levels of hope [29], perceived coping [27], carer wellbeing and support [23], and high levels of negative caregiving experiences [3, 30, 31]. There are no accepted norms of clinical cut-offs for these measures.
**Intervention and Support**

All participants allocated to the treatment arm received the REACT toolkit. Forty-seven relatives (92%) also had a face to face introductory session lasting between 35 and 90 minutes, with a median of 60 minutes (Inter-Quartile Range (IQR)=45–75). The number of subsequent support sessions (defined as contacts lasting 5 minutes or longer) ranged from 0–17, with a median number of 3 sessions (IQR=2–6). The length of support sessions ranged from 5–90 minutes with a median of 25 minutes (IQR=15–40). Total minutes of REACT supporter contact with relatives over the 6 month intervention period ranged between 0-855 minutes, with a median of 125.5 minutes (IQR=75-204).

Thirty one participants (61%) received support via telephone only, 6(12%) by email only, and 7(14%) had a combination of both. Three participants (6%) did not receive any additional support after the introductory session. Only 1 participant requested access to the online version of the toolkit.

Six NHS supporters were initially trained to support REACT. All had an interest in mental health. One had been a service user and one was a parent of someone with mental health difficulties. Although feedback about the training was generally positive, one dropped out during training due to leaving his post in the service, one dropped out following training due to changes in his role within the EIS team, and one was unable to continue due to ill health. Supporters who remained with the study worked flexibly to cover work across teams and additional input was required from one of the research team, a trained nurse therapist (DG) to support three participants.

**Treatment As Usual (TAU)**
Participants in TAU were asked to give an overall rating of how satisfied they were with the amount of help/support they had received from the EIS. Forty four people completed this measure. Of these 14(32%) were very satisfied, 14(32%) were mostly satisfied, 4(9%) felt indifferent, 9(21%) were only moderately satisfied and 3(7%) were not at all satisfied. Table 2 shows participants’ ratings of perceived support for each of the key elements of TAU. Deficits were most apparent in practical support, for example regarding finances, accommodation etc., and advice regarding stress management, for which at least half the sample did not feel they had received any support.

Insert Table 2 here

Table 2 – Relatives’ report of what support they had received in Treatment As Usual (TAU).

Impact on main outcomes

The estimated intervention effects (regression coefficient) shown in Table 1 indicate that relatives who received REACT showed a greater reduction in distress, negative experiences of caregiving, and concern about psychosis, along with increased positive experiences of caregiving, carer wellbeing and support, and perceived ability to cope (a high score indicates less coping) compared to those in TAU. However, only reduction in distress, increase in sense of being supported, and increase in perceived coping were statistically significant.

Fourteen of the 27 relatives (52%) categorised as clinical cases at baseline no longer reached this threshold in the REACT group, compared to only 7 of the 25 in TAU (28%). This difference just fails to reach statistical significance (Pearson’s chi-square
= 3.07, p = .08). No differences were found between groups for those who did not meet criteria for clinical caseness at baseline with 21% of these participants meeting threshold at follow-up in both arms. This suggests that REACT may be of clinical value to those scoring above threshold for clinical caseness but there is no evidence of a positive or negative impact on those scoring below, though much larger studies are needed to test this directly.

Quality Assurances

Despite attempts to maintain blindness, the second RA was unblinded to the allocation of 9 participants as a result of the relative having the toolkit visibly present at the interview or referring directly to the support they had received. Full blindness was maintained for the remaining 77 participants.

Discussion

Main findings and comparison with other studies

This study provides preliminary evidence for the feasibility and effectiveness of a supported self-management intervention for relatives of people experiencing recent onset psychosis in a real world clinical setting. Compared to similar studies recruiting families of people with psychotic disorders, relatives were keen to take part in the study, and follow-up rates were high [30, 32, 33]. Relatives showed high levels of distress [27, 28] and negative experiences of caregiving [3, 30] compared to previous studies with similar samples.

Compared to TAU only, those receiving the additional REACT intervention showed significant positive changes on a range of outcome measures including reduced distress, increased support, and increased perceived ability to cope. A trend was found
for increased well-being (p=.053). There were no significant differences between the
groups on negative or positive experiences of caregiving, concern about service user
behaviour, or hope, though all the non-significant differences observed were in the
direction favouring a more positive change for those receiving REACT.
These positive findings are consistent with evidence for the effectiveness of supported
self-management interventions to reduce distress in relatives of people with eating
disorders [15, 16] but are perhaps surprising given that the relatives in this study are
already in contact with EIS teams offering a very comprehensive package of support
for relatives. Despite having been with the teams for many months, the relatives were
still benefitting from this additional supported self-management approach. Relatives’
self-report of TAU suggests that this may be due to difficulties in delivery of family
support protocols as many did not feel they were receiving the interventions specified
in the NHS Trust policies. Self-management toolkits, such as REACT have the
potential to ensure some of these key elements, such as practical advice around
finance, accommodation etc., signposting to other relevant services, and advice on
stress management can be readily available.
The toolkit was supported by existing NHS staff. There were challenges in retaining
trained supporters to the study, and future use of the toolkit may benefit from training
more than one team member to accommodate sick leave and staff turnover. There was
a strong preference by relatives for a printed version of the toolkit and a moderate
preference for support by telephone. This was surprising given the recent explosion of
internet use and the success of online support for relatives in other areas [16] and may
be partly due to the recruitment strategy (which was via face to face contact, rather
than online), or a lack of promotion of the online options by supporters who were less
familiar with working this way.
The amount of support relatives received also varied considerably. This study is too small to examine quantitatively the role of the support and whether there is a minimum amount of support required for the toolkit to be effective. Indeed, it is possible that the support rather than the toolkit is the essential component, though research in eating disorders would suggest this is not the case [15].

**Study Limitations**

The study is a small feasibility trial. The findings suggest the REACT intervention can be effective in improving key outcomes for relatives but large confidence intervals indicate the need for replication in a larger trial to assess their reliability. This study focussed on an intervention for relatives aimed at improving outcomes for relatives. The impact on service user outcomes was not assessed, and no service user characteristics were controlled for. Based on interpersonal models of caregiving[34], we would hypothesise that improving outcome for relatives will have a positive impact on service user outcomes but further studies are needed to test this. However, this would require service users’ willing participation, excluding relatives who may be most in need of this kind of support. A key strength of REACT is that it is available to all relatives.

There was no attempt to assess the cost effectiveness of the intervention at this stage. The REACT intervention is designed to be a low intensity intervention that can be made widely available to all relatives. It therefore has limitations of being generic and limited in scope. However, it is not intended to replace high intensity structured family interventions which can offer a tailored formulation driven approach and should continue to be offered to families that require this level of input. REACT was
offered as an adjunct to TAU. However, TAU was not assessed in the REACT arm. It is possible that TAU varied between the arms which could bias the results.

Clinical Implications

There is a worldwide recognition of the need to develop new ways to disseminate psychological therapies in order to meet growing demand [35]. REACT offers a low intensity intervention for relatives of people with recent onset psychosis which has the potential to increase access to the key components of existing evidence based interventions. There is scope for future development of the REACT toolkit to include: peer support, interactive online programs and adaptation to the specific needs of relatives such as those from British Minority Ethnic groups (BME), young family members and siblings. The modular design of the toolkit format also lends itself to adaption to other clinical problems such as Bipolar Disorder.

Future Research

A larger trial is needed to reliably assess the clinical and cost effectiveness of the REACT intervention. This study should focus on long as well as short term outcomes and further attempt to identify the contribution of the toolkit and support in determining outcome. If the intervention is effective, subsequent research should focus on the most effective way to disseminate the intervention, and appropriate adaptations for different relatives of people with different diagnoses or from different ethnic or cultural groups. Identifying the optimal time to offer this kind of intervention to relatives is also important. It could be hypothesised that the earlier relatives receive this information, the more effective it may be as it ensures access to
information when it is needed. However, it may be that for some relatives too much information too soon can feel overwhelming and lead to it being ignored or even increasing levels of distress. Establishing mechanisms of action, and treatment moderators would help identify the key components to aid further development and dissemination.

(words excluding references and titles = 3992 )

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Role of Authors

FL as the PI oversaw the design, conduct and write up of the intervention study. DG, LW, LC, VP, GH, WL co-authored the toolkit, project managed the study, and contributed to the design of the study and writing of the paper. FL, DG, LC and LW trained and supervised the supporters. GD did the statistical analysis. AP collected
and prepared the data for analysis and contributed to the toolkit and write up of the paper. All authors approved the final version of the paper.
References


27. Barrowclough, C., et al., Factors associated with distress in relatives experiencing recent onset psychosis in a family member. Journal of Nervous and Mental Disease, Under Review.
Figure 1

Enrollment

Assessed for eligibility (n=144)

Excluded (n=41)
- Not meeting inclusion criteria (n=8)
- Declined to participate (n=21)
- Unable to contact (n=12)

Randomized (n=103)

Allocation

Allocated to intervention (n=51)

Allocated to treatment as usual (n=52)

Follow-Up

Lost to follow-up (unable to contact) (n=4)
Withdrawn (n=6)

Lost to follow-up (unable to contact) (n=3)
Withdrawn (n=4)

Analysis

Analysed (n=41)

Analysed (n=45)
Table 1. ANCOVA comparing follow-up scores controlling for baseline and team.

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<th></th>
<th>Mean (SD) (baseline)</th>
<th>Mean (SD) (FU)</th>
<th>Treatment Effect (95% Confidence intervals)</th>
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<th>P - value</th>
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<td>34.21 (15.67)</td>
<td>23.42 (15.20)</td>
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<td>REACT</td>
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</tbody>
</table>

GHQ = General Health Questionnaire

ECI = Experience of Care-giving Inventory

CWS = Carer Wellbeing and Support Questionnaire
### Table 2 – Relatives’ report of what support they had received in Treatment As Usual (TAU)

<table>
<thead>
<tr>
<th>Checklist to assess content of TAU</th>
<th>Frequency (% percentage of total sample n = 52)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Item</td>
<td>Fully</td>
</tr>
<tr>
<td>1. Do you think your needs as a carer / family member were assessed by the EIS team?</td>
<td>16 (39)</td>
</tr>
<tr>
<td>2. Were any problems that you were having identified?</td>
<td>15 (30)</td>
</tr>
<tr>
<td>3. Did you receive emotional support from the Early Intervention team?</td>
<td>10 (19)</td>
</tr>
<tr>
<td>4. Did you receive information about the mental health system?</td>
<td>17 (33)</td>
</tr>
<tr>
<td>5. Did you receive practical support, for example regarding finances, accommodation etc?</td>
<td>7 (14)</td>
</tr>
<tr>
<td>6. Were you informed about other services that may be able to help you, for example charitable organisations such as local example given?</td>
<td>6 (12)</td>
</tr>
<tr>
<td>7. Do you have contact details of someone that you can contact if your relative experiencing a crisis: 8am to 8pm?</td>
<td>32 (62)</td>
</tr>
<tr>
<td>8. Do you have contact details of someone that you can contact if your relative experiencing a crisis: Out of Hours?</td>
<td>30 (58)</td>
</tr>
<tr>
<td>9. Were you given any information regarding the nature of your relative’s mental health problems?</td>
<td>16 (31)</td>
</tr>
<tr>
<td>10. Were you given advice regarding stress management?</td>
<td>6 (12)</td>
</tr>
<tr>
<td>12. Was an assessment made of any possible risks of harm to your relative or someone else and a strategy agreed to manage these?</td>
<td>15 (29)</td>
</tr>
</tbody>
</table>