

Title:**Effect of digital psychoeducation and peer support on the mental health of family carers supporting individuals with psychosis – The COPE-support Randomised Clinical Trial****Authors' details**

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Title:**Effect of digital psychoeducation and peer support on the mental health of family carers supporting individuals with psychosis – The COPe-support Randomised Clinical Trial****Research in context****Evidence before this study**

We conducted two systematic reviews at the outset of the trial in 2016; one focusing on psychoeducation interventions for family carers of individuals with psychosis or schizophrenia delivered using any medium, and the second focusing on those delivered via the internet. For both reviews, we searched 10 databases covering medical and health (Medline, PsycInfo, CINAHL, Embase, Web of Science, ASSIA, Cochrane Central Register of Controlled Trials (CENTRAL), NIHR-Health Technology Assessment (HTA) database, Database of Abstracts of Reviews of Effect (DARE), and NHS Economic Evaluation Database (EED)), and grey literature (ProQuest dissertations and theses) for studies published in English and Chinese from database inception to December 1, 2016. The search terms comprised subject headings, synonyms and free-text search terms to identify (digital/e- or m-/web or internet-) psychoeducation interventions for family/informal/unpaid carer* for people affected by schizophreni* or psycho*. Searches were limited to randomised controlled trials. Through both reviews, we identified 32 RCTs including 2858 family carers, only one trial reporting an entirely digital intervention with 21 carers (and 31 patients) was identified. We conducted a meta-analysis, considering a range of mental health and caregiving-related outcomes. With relevance to this study, pooled results showed that psychoeducation, using a textual or face to face delivery format, was superior in reducing carers' global morbidities (standardised mean difference [SMD] -0.230), perceived burden (SMD -0.434), negative caregiving experiences (SMD -0.210), and expressed emotion (SMD -0.161), compared to usual care. Effects on carers' mental wellbeing were non-significant but data for this outcome were retrieved from just two trials and 184 participants. Only one trial investigated carers' quality of life as an outcome. The search focusing on trials of digital interventions targeting family carers was updated on December 20, 2020, identifying an additional trial investigating a digital self-management intervention which was facilitated by carer peer-workers but carers' mental wellbeing was not measured as an outcome.

Added value of this study

To our knowledge, this is the first full randomised controlled trial to report the clinical efficacy of a digital psychoeducation intervention providing quality health information and network support from professionals and carers as peers. This trial provides clear evidence that a

multi-component psychoeducation intervention delivered entirely online is not effective in improving carers' mental wellbeing when compared to a passive online information resource as control, at 20 weeks (primary timepoint). There was a significant increase in mental health knowledge at 40 weeks in the intervention group. The trial was indicative of a small to moderate increase in wellbeing, quality of life and positive caregiving experience, and a small reduction in negative caregiving experience and expressed emotion, at both 20 and 40 weeks; but these were statistically non-significant. Effects on mental wellbeing at 20 weeks were greater in participants with higher usage though this was not significant. Retention was high at 20 and 40 weeks with no adverse events or side effects reported, indicating it is feasible to deliver psychoeducation safely via the internet.

Implications of all the available evidence

Our study results suggest that digital multi-component psychoeducation intervention has no significant effect on carers' mental wellbeing and quality of life; outcomes which have long been under-researched in the evidence base of psychoeducation intervention effectiveness. In terms of caregiving-related outcomes more commonly reported in existing trials, such as caregiving experience and expressed emotion, our digital intervention was no more effective than the control. Our trial did not measure morbidities such as depression, anxiety or distress or perceived burden where a positive effect has been identified in systematic reviews on conventional psychoeducation interventions. Recruitment, retention and completion in the trial were satisfactory. Notwithstanding the need for good evidence of clinical and cost-effectiveness, the implication for policy is that digital psychoeducation intervention on its own should not be commissioned for carers supporting an individual with psychosis with an expectation of a significant impact on mental wellbeing and other health outcomes. However, we note that participants' usage of the digital intervention - in particular, posting on interactive forums - was highly heterogeneous and overall far below the recommended weekly login for half an hour. Considering the projected increase of carer population, it is not possible to meet these needs in primary care or specialist mental health service without exploiting the potential digital technologies offer. Further research to optimise the potential of digital technologies in delivering effective support, possibly adjunctive to professional-led and face-to-face services, including strategies to optimise engagement and increase usage, remains important.

Abstract

Background

Psychoeducation delivered face-to-face is effective in alleviating mental health morbidities in family carers of individuals with psychosis. However, research in such interventions delivered online is scarce. We evaluated the effectiveness of a digital multicomponent intervention, 'COPE-support' in improving carers' mental wellbeing and caregiving-related outcomes.

Methods

This parallel-group randomised controlled trial with analysis conducted masked to allocation was conducted online. Adults providing regular unpaid support for a relative or close friend affected by psychosis across England were recruited. COPE-support provided psychoeducation on psychosis-related caregiving strategies and forums with professionals and other carers; a passive online information resource acted as control. Primary outcome at 20 weeks was mental wellbeing measured by the Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) (minimally clinically important difference [MCID, 3]). Secondary outcomes included quality of life, caregiving experience, satisfaction with support, and expressed emotion at 20- and 40- weeks. This trial is registered with ISRCTN ([ISRCTN 89563420](https://www.isrctn.com/ISRCTN89563420)).

Findings/Outcomes

Between March 1, 2018 and February 14, 2020, 407 participants were randomised; 204 in the COPE-support group, and 203 in the control group. The participants (mean age 53.1 years, SD 13.2) were mostly female (330 of 407; 81%) and of White ethnicity (359 of 407, 88%). 346 (85%) participants provided primary endpoint data. The mean WEMWBS score was 44.5 (SD 8.31) for the COPE-support group and 43.3 (SD 9.19) for the control group; there was no evidence of a difference in wellbeing with adjusted mean difference of 0.37 (95% CI -1.14 to 1.88, $p=0.63$). In the COPE-support group, 106 (52%) met the complier definition of minimum two logins in separate weeks. The complier average causal effect analysis increased difference in WEMWBS scores (adjusted difference 0.89, 95% CI -1.4 to 3.2, $p=0.45$) but this was lower than the MCID. Similar results applied to all secondary outcomes at 20-weeks. There were no adverse events.

Interpretation

The findings did not support the use of COPE-support over a passive online information. However, further research to optimise digital interventions adjunctive to face-to-face support for carers remains important.

Keywords:

family carers; wellbeing; caregiving; mental health; psychosis; web/internet-based/digital/online

Introduction

Worldwide, a significant proportion of people provide substantial yet unpaid support and care to family members or friends living with a long term illness. In the UK, about 1.5 million people are carers supporting an individual with mental ill health.¹⁻³ Psychosis, including schizophrenia, is the most common severe mental illness (SMI).^{1,2} As onset peaks in late teenage or early adulthood, individuals with psychosis often require long-term treatment and support across a range of life domains.¹⁻⁵ Carers play a crucial role in sustaining their loved ones' community-based treatment and promoting their recovery.²⁻⁵ Conversely, caregiving negatively impacts carers' health and wellbeing.²⁻⁵

Clinical guidelines recommend psychoeducation to provide information on psychosis and its management for carers.^{1,6,7} Prior systematic reviews of clinical trials showed that psychoeducation which targeted carers as primary participants, with or without the patients' presence or involvement in the intervention, reduced carers' mental illness morbidities and caregiving-burden.^{1,2,4,5} These changes mediate carers' caregiving capacity,^{3-5,7,8} translating to reduced relapse and better prognosis for patients.^{4,5,7} However, implementation is limited;^{2,4,9} due to insufficient resources in routine health services, and carers' difficulties in attending among multiple commitments.^{2,9} Although the internet offers a novel, accessible and self-paced approach to deliver mental health interventions which address some of these barriers,¹⁰⁻¹² only one pilot¹³ and one full¹⁴ randomised trials evaluated such interventions in the field of psychosis caregiving to date.

Effective psychoeducation interventions for carers often comprise evidence-based health information and strategies to address commonly encountered challenges in psychosis caregiving, led by professionals and using a group format to enable exchanges of experiences and support among peers.^{4-5,11} Although most psychoeducation interventions tend to last for on average 20 weeks given their goals in imparting cognitive and behaviour changes in carers, previous meta-regression revealed no significant associations between intervention duration or contact time and outcomes.⁴ We previously developed and tested the usability of an entirely web-based multicomponent intervention called COPe-support.^{15,16} This study examined whether COPe-support improved carers' mental wellbeing, health- and caregiving-related outcomes, compared with a passive online information resource as control.

Methods

Study design

The trial used a two-arm, individually randomised controlled superiority trial design comparing COPE-support to a passive online information resource. It had an internal pilot trial to test the trial procedures, recruitment and retention, running in the first 12 of the 30 months trial duration. The pilot stop-go criteria included: to recruit at least one third of the sample size; to retain at least 80% of participants; with over 80% of them having activated their logins. A detailed trial protocol has been published.¹⁷ The UK National Health Service (NHS) Health Research Authority approved this study (reference: IRAS 240005). All participants provided informed consent via the study online platform. Significant patient, carer, and public involvement (PPI) activities underpinned the design and conduct of the study. We have eight patient-, carer- and key stakeholder members among our 14-membered Project Reference Group which oversaw the study design, identified the outcomes and measures used in the study, supported the study delivery, data analysis and dissemination of the study results.¹⁵

Participants

The trial included relatives and close friends aged 18 years or over who (1) provided at least weekly support in any format for the cared-for person (CfP) who had psychosis;¹ (2) had daily access to the internet including emails; and (3) were able to communicate in English. Both the carers and the CfP were required to reside in England, UK during the study period. To avoid a clustering effect, potential participants who had another relative or friend sharing the caring role for the same CfP already enrolled in the study were excluded. Enrolment occurred between 1 March 2018 and 14 February 2020.

Participants were recruited through 30 mental health National Health Service (NHS) trusts (provider organisations) across England. We advertised through: flyers and posters; asking healthcare workers to inform potentially eligible carers; national and local voluntary organisations which provide support for carers; our study website (www.cope-support.org) and social media communications with relevant organisations.

Potentially suitable participants completed an online eligibility screening process through our research website. Queries were resolved and further information provided through phone or online discussion with the study coordinator. Those eligible provided online written consent.

Randomisation and Masking

An independent online system randomised participants in a 1:1 ratio, stratified by gender and recruitment cohort. A permuted block randomisation scheme included randomly selected sized blocks of 2 and 4. Over the study duration, we scheduled participants into 6 cohorts, placed 4 months apart to ensure optimal numbers i.e. $20 \leq n \leq 60$ in each arm.^{4,11}

Randomisation was performed in order of baseline data collection in the 4 months recruitment time prior to each cohort starting. Study team were masked to allocation and assessment of outcomes as all data collection took place online. It was not feasible to mask participants or the online facilitator to intervention allocation. Statistical analyses were performed masked to allocation.

Procedures

Participants received an email providing unique login details to access the allocated intervention, together with instructions to download the free app (Apple or Android) which enabled usage through smart phones/tablets in addition to computers via web browsers. Participants had access to either condition for 40 weeks and were advised to spend at least half an hour per week over the initial 20 weeks, to go through materials at their own pace and to allow time to integrate knowledge and skills learnt into practice. An experienced mental health nurse (JS) acted as the online facilitator who monitored and moderated all the interactive functions. The online facilitator sent weekly updates via the intervention announcement function which generated an email automatically to participants to promote engagement. For security and anonymity, participants were required to follow ground rules including the use of a self-chosen pseudonym and not give any of their or their CfP's identifiable details on the platform.^{15,16}

COPE-support – Intervention

COPE-support was co-designed and co-produced with people with lived experiences of psychosis or caring experience, and key stakeholders working in the field, through a participatory research study.¹⁵ Our considerations of the intervention content and key ingredients, duration and intensity (i.e. 20 weeks), and facilitation strategies (e.g. moderation, anonymous participation) had also been informed by our theoretical development work.^{4,11} During the intervention-build process, 24 carers independent from the study reviewed and gave feedback to the early versions of the prototype.¹⁵ A mixed methods usability study incorporating a think-aloud test and remote usability test was conducted in 20 carers over three months, from 1 November 2017 to 31 January 2018, to establish the feasibility of delivering COPE-support via the internet.¹⁶ (See Supplement 1 for intervention content)

COPE-support was a multimedia, interactive intervention providing psychoeducation and network support with peers and professionals, delivered through the web-based learning environment Canvas (<https://www.canvasvle.co.uk>). In addition to the Home page which provided a menu, navigation video and guide, the intervention comprised 12 sections. These included psychoeducation on psychosis, its treatment and related caring issues, wellbeing

promotion information and exercises, an “Ask the Experts” online forum where participants could ask for advice from 14 experts including multi-disciplinary clinicians, welfare benefits advisors, and people using mental health services, a “Peer to Peer” forum where participants exchanged views and support, a “Resources for Carers” section providing extensive links to relevant external resources (such as statutory and professional bodies, charities, books, online information sites), and a “Support” weblink for participants to seek technical or emotional support if necessary. There was no prescribed order or sequence on the content; instead, participants were encouraged to pick the content specific to their own needs and caring situations. Participants were able to initiate posts and respond to both “Ask the Experts” and “Peer to Peer” forums or visit both forums passively, i.e. reading posts.

Information Resource - Control

A web-based information resource run on a parallel Canvas platform acted as the control which had the identical “look and feel” as COPe-support. The control comprised the Home page, “Support” function and all the information provided under “Resources for Carers” in COPe-support. There were no interactive elements included in the passive online information resource platform, similar to other information websites as the most common provision within the wider usual care. To optimise retention, control group participants were given access to COPe-support for 20-weeks, after completing 40week follow-up data collection.

All participants had unrestricted access to usual care which commonly comprised information and advice sought from primary care or NHS mental health service or voluntary organisations. As usual care for carers varies geographically and based on participants’ circumstances, we collected health, social, voluntary and other service use data from participants.

Outcomes and Measures

Primary Outcome

The primary outcome was mental wellbeing at 20-weeks, assessed by the Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS).¹⁸ The WEMWBS has been widely used to measure positive mental health at the population level;¹⁹ its scores range from 14 to 70 with higher scores indicate better wellbeing,¹⁸ and a change of 3 points represents the minimally clinically important difference (MCID).¹⁹

Secondary Outcomes

Secondary outcomes at 20-weeks were as follows. Quality of life was measured using the EQ-5D-5L visual analogue scale (VAS), on which higher scores represent better subjective

judgement of health state.²⁰ Mental health knowledge was measured using the Mental Health Knowledge Schedule (MAKS); higher scores indicate better stigma-related mental health knowledge.²¹ Appraisal of caregiving experience was measured using Experience of Caregiving Inventory (ECI) which has positive subscales for which higher scores indicate better experience; and negative subscales with higher scores indicating poorer experience.²² Carers' wellbeing and satisfaction with support was measured using the Carer Wellbeing and Support Scale (CWS); higher wellbeing subscale scores indicate higher wellbeing, while higher support subscale scores with reversed scoring indicate worse satisfaction.²³ Carers' expressed emotion (EE) in terms of criticism and over-involvement was measured with the Family Questionnaire (FQ), on which higher scores indicate higher EE.²⁴

Study outcomes were assessed at baseline, mid-treatment (10-weeks), 20-weeks (primary endpoint) and 40-weeks follow-up. All primary and secondary outcomes were self-report measures completed by participants online. At baseline, participants were asked to provide demographic data and information on their caregiving situation such as time spent caregiving per week, relationship with the CfP, and minimal, non-identifiable information about the CfP comprising age, gender, specific psychotic disorder type and time since illness onset.¹⁷

Other outcomes

For safety monitoring, in addition to adverse events (AE) and serious adverse events (SAE), we devised a category labelled as "unintended consequences (UC)" to denote incidents of access-interruptions to the interventions. All safety events were documented, categorised and evaluated by an independent Trial Steering Committee.¹⁷

We pre-specified usage data at 20-weeks which were automatically recorded by the online platform,¹⁷ including: number of logins in separate weeks; average page views; total time spent on the platform; and average time spent per page view, for both groups. For COPe-support group, numbers of posts per participant made to each forum were recorded. These are most commonly recorded digital health intervention usage metrics reported in similar studies.¹⁰⁻¹⁴

Perceived acceptability of COPe-support was obtained through individual interviews after 40-weeks follow-up with 20% of the intervention participants. These data are reported separately.²⁵

Statistical Analysis

Sample Size and Power Calculations

To detect a MCID of 3 for the between-group difference in WEMWBS score,²⁰ assuming a standard deviation of 9²⁶ a sample size of 360 participants was required with $\alpha=0.05$ (2-tailed) at 80% power while accounting for 20% dropout.

Analysis plan

Our primary estimand was the effect of COPE-support for all participants regardless of usage (Treatment Policy Estimand),²⁷ including participants with at least one post-baseline assessment in their allocated groups (intention-to-treat principle). We used a linear mixed model to estimate the mean difference in WEMWBS score between arms at 20-weeks. The model included baseline score, 3 indicators for each timepoint (10, 20 and 40 weeks), indicator for intervention allocated, a timepoint and intervention interaction, gender (stratification variable), parent (Y/N) and living with the cared-for individual (Y/N) as fixed effects with cohort and subject as random effects. The model was fitted using restricted maximum likelihood and assumptions were checked through residual plots. A further analysis estimated the intervention effect for the subsample of intervention compliers (Intervention Efficacy Estimand). We pre-defined “compliers” as participants in the COPE-support group who made at least two logins in separate weeks by week 20, i.e. those who had chosen to return to the intervention after their initial successful login activation. We performed a complier average causal effect (CACE) analysis²⁸ using a two-stage least squares regression with randomisation as the instrumental variable. We also performed post-hoc CACE analysis to assess intervention effects of different usage thresholds as alternative complier definitions.

A sensitivity analysis explored the impact of missing data and departures from the Missing-at-Random (MAR) assumption on the primary estimand, using controlled multiple imputation. Imputations were performed separately within each intervention arm using variables in the primary model and auxiliary variables identified as strongly associated in previous work.³ A further sensitivity analysis was also performed using multiple imputation across every timepoint to include all participants.

The intervention difference for all secondary outcome measures was estimated as the treatment policy estimand, using linear regression models including intervention arm, baseline score, gender and cohort. The analysis was performed separately at each timepoint (10, 20 and 40 weeks), with the primary focus at 20-weeks. Incidents of AE, SAE and UC were tabulated showing number of events and number of participants per arm. Analyses were conducted with Stata version 15. The trial was registered prospectively in the International Standard Randomised Controlled Trial Registry

(<https://www.isrctn.com/ISRCTN89563420>) and its detailed protocol has been published.¹⁸

(See online appendix 1)

Role of the funding source

The study was funded by the UK National Institute for Health Research under its Post-Doctoral Research Fellowship (Ref.: PDF-08-035). The funders had no role in the study design, data collection, data analysis, data interpretation, writing of the report, or the decision to submit the paper for publication.

Results

Recruitment ran between 1 March 2018 and 14 February 2020. During this time, there were 695 visits to the online study enrolment platform; 527 undertook eligibility screening with 465 confirmed as eligible. Between 1st March 2018 and 14th February 2019, 189 of the participants were recruited into the internal pilot. Criteria for the internal pilot were met and the trial steering committee approved the trial to progress. Four hundred and seven participants completed baseline assessment and were randomised with 204 allocated to COPe-support and 203 to control. The last participant completed their final visit in October 2020. There were 4 (2%) withdrawals from the intervention (n=204) and 6 (3%) from the control (n=203) group. Figure 1 shows the flow of participants through the study.

[Insert Figure 1 about here]

Baseline characteristics and usage

Table 1 presents the characteristics of randomised participants; the baseline characteristics appeared to be balanced between groups. The mean age was 53.1 years (standard deviation 13.2), 330 (81%) of 407 were women, 258 (64%) of 407 were parents, 359 (88%) of all participants were White, and 197 (49%) of 407 had been caring for under 5 years. The majority were recruited across seven regions of NHS mental health services in England. During the first 20-weeks, 355 (87%) of 407 participants activated their logins; 175 (86%) of 204 in the intervention and 180 (89%) of 203 in the control group. The COPe-support group logged in a median of 4.0 times (interquartile range [IQR] 2.0-7.0) with median usage time of 69.7 minutes (IQR 17.3-176.1). Control participants logged in a median of 2.0 times (IQR 1.0-4.0) with a median usage time of 20.4 minutes (IQR 9.1-38.8). (Supplementary Table 1 reports usage data)

[Insert Table 1 about here]

Effects on primary outcome

The primary analysis included 174 (86%) of 204 COPE-support and 172 (85%) of 203 control arm participants. The mean WEMWBS score at 20-weeks was 44.5 (SD 8.31) and 43.3 (SD 9.19) for the COPE-support and control arm respectively (Figure 2). The adjusted between arm mean difference in WEMWBS score was 0.37 (95% CI -1.14 to 1.88, $p=0.63$), providing no evidence for a statistical difference between arms (Table 2). A sensitivity analysis to explore the impact of missing data resulted in an estimated range from 0.09 to 0.75 (Supplementary Table 2) at 20-weeks. A further supplementary analysis including all participants randomised was 0.24 (95% CI -1.43 to 1.91) at 20-weeks. The additional analysis was consistent with the original conclusions.

The adjusted mean difference between arms at 10-weeks was 1.05 (95% CI -0.43 to 2.53, $p=0.17$). At 40-weeks follow-up, the adjusted between arm mean difference was 0.37 (95% CI -1.16 to 1.89, $p=0.64$) (see Table 3).

[Insert Figure 2 about here]

[Insert Table 2 about here]

[Insert Table 3 about here]

The primary CACE analysis included 156 (77%) of 204 participants in the intervention and 154 (76%) of 203 in the control group. In the intervention arm, 106 (52%) of 204 participants met the pre-specified complier definition (i.e. ≥ 2 weekly logins). Their mean WEMWBS score at 20-weeks was 44.8 while compared to 42.9 for the would-be-compliers in the control arm. The adjusted between arm difference in WEMWBS score was 0.84 (95% CI -1.46 to 3.15), providing no evidence for a statistical difference between arms. The efficacy estimate was greater than the treatment policy estimand in favour of COPE-support but not close to the MCID of 3. Post hoc analyses using different complier definitions resulted in an estimated range of between arm difference from 0.88 to 1.48 and was greatest in those who had spent over 120 minutes on COPE-support platform by 20-weeks (Table 4). The additional analysis was consistent with the original conclusions.

[Insert Table 4 about here]

Effects on secondary outcomes

Results from secondary outcomes analysis were similar to that of the primary outcome (see Table 2). The adjusted 20-weeks between arms difference were small in magnitude for all secondary outcomes and there was no evidence for a significant statistical difference. The point estimates for six of these were in favour of the COPE-support arm (MAKS, ECI Positive and Negative subscales, EQ-5D-5L VAS, FQ and CWS-Support) and one (CWS-Wellbeing) in favour of the control. At 40-weeks follow-up, similar results for all secondary outcomes, apart from mental health knowledge were found; the intervention group had statistically

significantly higher MAKS (0.64; 95% CI 0.11 to 1.18, $p=0.02$) than the control (see Table 3 for analysis at 10-weeks and 40-weeks).

Adverse Events

No AE nor SAE were reported. There were 21 UCs reported by 20 participants: 10 in the intervention; and 11 (by 10 participants) in the control groups. All UCs were related to problems in activating logins or accessing the interventions.

Discussion

Principal findings

Among carers supporting an individual with psychosis, using COPE-support providing web-based interactive psychoeducation and network support for 20-weeks did not significantly improve mental wellbeing compared with a passive online information resource. Similar results applied to all secondary outcomes at 20 and 40 weeks with the exception of stigma-related mental health knowledge which reflected a more positive outlook on treatment effectiveness and on recovery. While mental wellbeing and a range of caregiving-related and mental health outcomes improved among COPE-support participants; COPE-support was not superior to the control.

Our trial results echoed that of a recent study of an online self-management intervention facilitated by trained peer-workers for carers of people with psychosis in England.¹⁴ We consider the potential explanations for the results. First, overall usage of COPE-support was below our recommended weekly 30-minutes use for 20-weeks. Heterogeneous usage and adherence has been frequently observed in digital mental health interventions, in particular in self-guided ones.^{10-14,29} While face-to-face psychosocial interventions commonly have in-built engagement sessions which have been shown to mediate therapeutic alliance, adherence and effects,^{4,5,30} online interventions such as COPE-support may fall short in establishing engagement with participants relying solely on online communications, hampering ongoing content delivery.^{10-12,29} Our CACE analysis showed a greater effect in participants with higher usage though this difference was not significant. This raises the possibility that lack of significant effect was, in part, because of low or no minimally sufficient treatment dosage. However, there is currently insufficient research to indicate the required compliance threshold.^{11,29} Second, while the effectiveness of face-to-face psychoeducational interventions in reducing psychological distress and burden is well-established,^{4,5} the pathways to positive effect on carer mental health remain unclear. Third, while participants reported feeling better supported through COPE-support, it is possible that they did not observe clinical improvement in the people they were caring for, therefore their own

outcomes did not change. Nearly all the participants were recruited through mental health services, indicating that the carers were supporting an individual receiving care at the time of the study. This might imply the participants' need for support was high and beyond what COPE-support was designed for. Fourth, participants across groups had access to health information resources and usual care, potentially contributing to a larger control group effect. Prior conventional psychoeducational intervention trials commonly used waitlist or usual care as comparison and so a tougher test of effect was applied here.^{4,5}

Strengths and limitations of this study

The strengths of this study were its large sample size, broad inclusion criteria considering the varied nature of caregiving in psychosis (such as different relationships between carers and CfPs, time spent on caregiving), a web-based active control group to reduce confounding factors inherent in technology or delivery medium, and use of methods designed to reduce the risk of bias such as participant-reported outcome measures, statistical analysis performed masked to allocation, intention-to-treat analyses, and pre-registered statistical analysis plan. The limitations primarily include the following. Our results may be more generalisable to individuals who are comparable with the study sample, the majority of whom were women, White, and used internet communications regularly. We recruited carers as participants across England where, although health services share the same systems and clinical guidelines,¹ variation in care and resources available for carers across areas does exist. While the randomisation should have removed any allocation bias, we did not pre-specify the areas from where carers or their CfPs resided as a stratification factor. Similar to many other psychotherapy trials, participant masking was not possible; this might have led to bias by expectation, considering that all outcomes were self-reported.

Implications for policy and practice

Psychoeducation, delivered as a group programme facilitating exchanges of experiential knowledge and support between peers, is among the most effective interventions recommended for carers supporting an individual with psychosis.^{1,2,4,5,7} Paradoxically, implementation of such interventions is limited. Self-guided digital interventions, like COPE-support, offer full user autonomy and require minimal inputs from healthcare professionals. A high proportion of carers remained engaged with the intervention over 40 weeks, with no adverse events reported over the 30 months study duration. These suggest that digital technology can be used efficaciously meeting carers' needs for psychoeducation and network support across a vast geographical area. Our study findings on improved stigma-related mental health knowledge among carers also suggest that COPE-support may therefore have had benefits in relation to knowledge rather than to wellbeing and health outcomes; this will be explored further in the qualitative analysis of participant interviews.

Further research is also needed to explore the effects of peer workers or peer researchers instead of clinicians acting as online forum facilitators or study coordinators, in both usage and nature of interactions. COPe-support, adapted with better digital engagement strategies which promote higher usage and as an adjunct to some face-to-face support from local services, may have the potential to fill an important gap in delivering high quality psychoeducation to carers. Considering the strong association between the carers' own wellbeing and their caring capacity, which inevitably impact on the recovery of the person they care for,^{3,8,9} interventions targeting carers, as both users and providers of care, can have far-reaching effects. Also, with the implementation of digital interventions, accelerated in light of the Covid-19 pandemic to overcome face-to-face contact restrictions, further research is warranted to investigate strategies to optimise usage and effects of carer-focused digital interventions. With the projected increase of the carer population, many of whom are unable to attend or have no access to in-person interventions, it is not possible to meet these needs in primary care or specialist mental health services without exploiting the potential of digital technologies.

Conclusions

Our results show that for carers supporting an individual with psychosis, COPe-support providing online psychoeducation and support from professionals and peers was not superior to a high-quality passive information resource as control, in improving mental wellbeing at 20-weeks. The findings do not support the use of COPe-support in its current format over a passive online information resource. Considering the projected increase of carer populations and demand for support, delivering evidence-based interventions via the internet adjunctive to face-to-face services remains a potentially viable option.

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Figure legends

Figure 1. Participant Enrolment, Randomisation, and Follow-up in the COPe-support Trial

Figure 2: Unadjusted mean WEMWBS score across the 4 timepoints by treatment arm

Declarations

Ethics Approval and Consent to Participate

This study has been reviewed and approved by South Central – Oxford C Research Ethics Committee (Reference: 18/SC/0104) and Health Research Authority (Reference: IRAS 240005). Prior to study participation all participants viewed and consented to the information that was provided in the Participant Information Sheet.

Consent for publication

Not applicable

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Competing interests

All authors have completed the ICMJE uniform disclosure form and declare:
no support from any organisation, other than the NIHR as funder as described above, for the submitted work;
no financial relationships with any organisations that might have an interest in the submitted work in the previous three years;
no other relationships or activities that could appear to have influenced the submitted work.

Authors' contributions

JS led the study at all stages with guidance from CH, VC, and SG. CH, JE, VC, LW, TC, and SG helped design the study. JS wrote the trial protocol with input from CH, SG, VC, LW, and TC. VC, TC, JE and JS designed and wrote the statistical analysis plan. JS, RB, JE, and VC (JE and VC are independent trial statisticians) verified the underlying data. JE and VC did the statistical analysis; JS, VC, TC, JE, CH, and SG interpreted the analyses. JS managed the study with input from RB and LW. JS, CH, AMC, DC, DR, SE, BH, SM, AOB, MQ, JSs, CT, EW, and LW implemented the study with JS acting as online intervention facilitator. JS, LW, and RB collected data. JS wrote the first draft of the report with input from JE, VC, CH and SG. All authors had full access to all of the data including the raw data sets, and contributed to drafting the report. All authors read and approved the final version of the manuscript and take responsibility for its content.

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Data sharing

Individual participant data that underlie the results reported in this article, after de-identification (text, tables, figures, and appendices) will be shared by the corresponding author (Jacqueline.sin@city.ac.uk), upon reasonable request for academic and research purposes, and subject to Data Sharing Agreements and approval of Health Research Authority and NHS Research Ethics Committee. The statistical analysis plan is available as supplementary materials; analytical code will be made available to researchers to researchers upon reasonable request addressed to the lead statistician (v.cornelius.ac.uk).