

## Effectiveness of psychoeducational interventions for family carers of people

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#### Review

### Effectiveness of psychoeducational interventions for family carers of people with psychosis: A systematic review and meta-analysis



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#### ABSTRACT

Psychoeducational interventions for family carers of people with psychosis are effective for improving compliance and preventing relapse. Whether carers benefit from these interventions has been little explored. This systematic review investigated the effectiveness of psychoeducation for improving carers' outcomes, and potential treatment moderators. We searched for randomised controlled trials (RCTs) published in English or Chinese in eight databases. Carers' outcomes included wellbeing, quality of life, global morbidities, burden, and expressed emotion. Thirty-two RCTs were included, examining 2858 carers. Intervention duration ranged from 4 to 52 weeks, and contact times ranged from 6 to 42 hours. At post intervention, findings were equivocal for carers' wellbeing (SMD 0.103, 95% CI - 0.186 to 0.392). Conversely, psychoeducation was superior in reducing carers' global morbidities (SMD - 0.230, 95% CI - 0.386 to - 0.075), perceived burden (SMD - 0.434, 95% CI - 0.567 to - 0.31), negative caregiving experiences (SMD - 0.210, 95% CI - 0.396 to - 0.025) and expressed emotion (SMD - 0.161, 95% CI - 0.367 to - 0.045). The lack of available data precluded meta-analysis of outcomes beyond short-term follow-up. Meta-regression revealed no significant associations between intervention modality, duration, or contact time and outcomes. Further research should focus on improving carers' outcomes in the longer-term and identifying factors to optimise intervention design.

#### 1. Introduction

Psychoeducational interventions, generally defined as information provided about a condition and its management, are proven to be effective for improving compliance in psychosis, and in reducing relapse (National Institute for Clinical Excellence (NICE), 2014; Xia, Merinder,-& Belgamwar, 2011). Psychoeducation is commonly delivered via individual or group programmes, and involves clinicians taking on the role of information-provider, and patients and family carers as participants (Sin, Jordan, Barley, Henderson, & Norman, 2015; Sin & Norman, 2013; Xia et al., 2011). More recently, interventions delivered via eHealth (internet-based) or mHealth (using mobile apps) have also garnered increasing interest and usage, perhaps augmenting conventional face-to-face formats (Alvarez-Jimenez et al., 2014; Cavanagh et al., 2006; Chi & Demiris, 2015;

Glynn, Randolph, Garrick, & Lui, 2010; Proudfoot et al., 2004; Sin, Henderson, & Norman, 2014; Sin, Moone, Harris, Scully, & Wellman, 2012). Multi-component programmes, which comprise peer support and discussion with others in a similar position, information about coping strategies and problem solving techniques for common illness-management or care-related issues, have become increasingly popular (Gillard, Gibson, Holley, & Lucock, 2015; Lobban, Postlethwaite, et al., 2013; Sin, Moone, & Newell, 2007; Sin, Moone, & Wellman, 2005; Sin & Norman, 2013; Xia et al., 2011). Involvement of family carers in psychoeducational interventions, with or without patients, has been identified as a pivotal mechanism for promoting patients' outcomes (NICE, 2010; Xia et al., 2011; Yesufu-Udechuku et al., 2015). In general, it is hypothesised that the effectiveness of psychoeducation is contingent on carers' knowledge about psychosis, their cognitive appraisal about the caring situation, and

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subsequently, their perceived burden and (self-efficacy in) coping with caring (Bandura, 1977a, 1977b, 1988; Birchwood, Smith, & Cochrane, 1992; Lazarus & Folkman, 1984).

Carers' perceived burden and appraisal about their ability to manage the caring for a loved one with psychosis, are well established as being highly correlated with their wellbeing and global morbidities (Guerriero Austrom et al., 2015; Kuipers, 2010; Kuipers & Raune, 2000; Smith et al., 2014). That is, the burden of caring can incur clinically significant levels of stress and distress in carers themselves, increasing vulnerabilities to both physical and mental health morbidities. Furthermore, studies have identified that carers' wellbeing is associated with their caregiving capacity; that is, poorer wellbeing affects propensity to provide adequate support, which in turn is believed to be influential in shaping patients' prognosis and relapse rates (Johnson et al., 2000; Kuipers, Onwumere, & Bebbington, 2010; Smith et al., 2014). Based on the stress-appraisal-coping theory as applied in family caregiving (Lazarus, 1966; Lazarus & Folkman, 1984; Szmukler, 1996; Szmukler et al., 1996), it has long been hypothesised that psychoeducation, with education as its core features and prime aim, works directly in improving carers' knowledge about psychosis and related caregiving issues. Improved knowledge about coping strategies and resources can lead to a more positive appraisal of their caregiving experiences as well as carers' own self-efficacy in coping with the demands. These, in turn, can translate into decreases in perceived burden and global morbidities (Joyce, Leese, & Szmukler, 2000; Joyce et al., 2003; Szmukler, 1996). It is possible that these caregiving-related outcomes would mediate into better carers' wellbeing and quality of life (Joyce et al., 2003; Kuipers et al., 2010; Martens & Addington, 2001; Szmukler, 1996). However, little is known about the specific impact of such interventions on family carers' outcomes, potentially because: (1) carers' outcomes are often reported as secondary to those of patients in trials, despite carers often being the sole participants (Sin & Norman, 2013; Sin et al., 2015; Xia et al., 2011); (2) most carers are not recipient of health and/or social care services, and hence their needs are not considered to take priority (Kuipers, 2010); and (3) the significant heterogeneity of interventions tested and broad-ranging carer-outcome measures used, rendering pooling of data for meta-analysis difficult (Lobban, Postlethwaite, et al., 2013; Miyar & Adams, 2013; Sin & Norman, 2013).

While previous systematic reviews on psychoeducation have been undertaken, none of these have solely included randomised controlled trials (RCTs), nor sought to undertake meta-analyses on carers' outcomes (Lobban, Postlethwaite, et al., 2013; Sin & Norman, 2013; Sin et al., 2015). The current systematic review had two aims:

- to assess the effectiveness of psychoeducation on family carers' wellbeing, health morbidities, and caregiving-related outcomes; and
- (2) to identify intervention-factors (such as intervention duration, contact time, and different modes of delivery), which may moderate intervention effectiveness. Understanding these factors further is likely to enhance the development of more targeted interventions.

#### 2. Method

We published the review protocol in PROSPERO (International Prospective Register of Systematic Reviews) (Sin et al., 2016). The review process followed PRISMA guidelines (Moher, Liberati, Tetzlaff, Altman, & Group, 2009).

#### 2.1. Search strategy

We followed the search strategy originally developed for our earlier review (Sin & Norman, 2013). Key search terms were devised using the Cochrane Schizophrenia Group and Central Register of Controlled Trials (CENTRAL), synonyms for "schizophrenia", "psychosis" and "psychoeducation\* intervention\*", in combination with free text to

maximise the sensitivity of the search. We searched for RCTs published from the date of inception to 31st May 2016 in eight databases: MEDLINE (via Ovid); PsycINFO; CINAHL; EMBASE; Cochrane Reviews Library; CENTRAL; Web of Science and ASSIA. In addition, the reference lists of all included studies and of relevant existing systematic reviews were checked for further possible studies. Authors of studies screened were contacted for information regarding unpublished data and ongoing trials.

#### 2.2. Inclusion and exclusion criteria

In order to extract data for meta-analyses and meta-regression, only RCTs (including cluster and crossover trials) were eligible. We included studies which investigated psychoeducational interventions which primarily aimed to provide information about illness and symptom management, involved interaction between information providers and participants, and were delivered via any modalities or a combination of modalities (Sin & Norman, 2013; Sin et al., 2016). We included interventions which were professionally-led, although those which involved co-facilitation from a family carer or other lay-person were not excluded. Pure bibliotherapy, and treatment programmes that solely relied on educational materials (such as booklets or non-interactive websites), but which comprised no actual interaction, were excluded. Considering that psychoeducational interventions commonly aim to change complex behaviours and attitudes, we excluded interventions that had a duration shorter than 4 weeks, but imposed no upper limit on intervention duration.

The population studied was informal or family carers of any age (excluding paid, professional or formal carers), of individuals affected by psychosis however defined and treated in any setting. Family carers could be either biologically (e.g. parents, siblings) or non-biologically (e.g. spouses, close friends) related to the patients. Carers could attend the interventions with or without the patients.

Comparators reported in the control arms were categorised into two types:

- inactive controls which included waitlist, standard, usual care and/ or 'attention-control'; and;
- (2) active controls which comprised alternative active interventions targeting family carers, other than psychoeducational in principle, whose content, mode of delivery and design were clearly described. Examples of active controls included cognitive behavioural therapy, counselling, or family intervention.

#### 2.3. Study selection, data extraction and risk of bias assessment

Initial screening of study titles, abstracts and full text articles was undertaken by two authors (JS and DS) independently and in parallel. Data extraction from included papers was also undertaken by JS and DS independently, and reviewed by VC and TC as required. The Cochrane Collaboration risk of bias tools for RCTs (Higgins & Green, 2011) were used to assess quality of studies and evidence, again by JS and DS independently. At each stage, the whole review team reviewed the searches, abstract and full-text screening, and data extraction results. We resolved uncertainties through: (1) seeking additional data or clarification from trialists when possible; and (2) review team discussion and consensus.

#### 2.4. Outcomes and measures

The primary outcome measures were the standardised mean difference (SMD) in three carers' outcome domains: wellbeing; quality of life; and their proxy measures such as stress, global morbidities (including poor physical and/or psychological health), and depression. Secondary outcomes focused on common caregiving-related outcomes such as: positive and negative appraisals of caregiving experiences;

perceived burden; 'expressed emotion' (commonly measured as hostility and criticism towards the patient) (Bebbington & Kuipers, 1994; Brown, Monck, Carstairs, & Wing, 1962; Kuipers & Raune, 2000; Raune, Kuipers, & Bebbington, 2004); family functioning, perceived social support, and knowledge. Only data from validated outcome measures were included in the meta-analysis and meta-regression. Outcome data were grouped according to the following time points: end of intervention; up to 6-month follow up; longer than 6-month but up to 12-month follow up; and over 12-month follow up. For outcomes measured at several time points within these intervals, we reported the analyses separately.

#### 2.5. Analysis strategy

The analysis began with an overview of study characteristics followed by tabulation of extracted data, in STATA version 13 [StataCorp. 2013. Stata Statistical Software: Release 13]. In addition to conducting overall analyses comparing psychoeducational interventions with all comparators pooled together, we also conducted separate comparisons on psychoeducational interventions with all inactive controls pooled together, then proceeded to compare psychoeducational interventions against active controls grouped together according to their shared modalities whenever there were sufficient data extracted from the included studies. Considering the outcomes were measured with different validated scales, we therefore calculated standardised mean difference (SMD) and 95% confidence interval (CI) for continuous outcomes; and, risk ratio (RR) and its 95% CI for dichotomous data (Egger, Smith, & Altman, 2001; Higgins & Green, 2011); using the random effects model (Higgins & Green, 2011). Statistical heterogeneity was quantified using the I-squared (I2) statistic (Higgins, Thompson, Deeks, & Altman, 2003). We interpreted I<sup>2</sup> values around 50% or above as evidence of substantial levels of heterogeneity. When heterogeneity was identified, we explored reasons for the inconsistency through prespecified subgroup analysis. In general, the magnitude of SMD is interpreted as follow: small = 0.2; medium = 0.5; large  $\geq$  0.8 (Egger et al., 2001; Higgins & Green, 2011). Moreover, the effect size should be interpreted within the context of overall quantity (such as number of studies and participants) and quality (such as methodological quality of studies and heterogeneity across studies) of the data included in the meta-analysis.

We also undertook meta-regression to investigate intervention-factors, namely: treatment contact time (in terms of hours as continuous measures); treatment duration (in terms of weeks as continuous measures); and the modes of delivery using group or individual format (as categorical measures), when data from at least eight studies were available (Higgins & Thompson, 2004). Such intervention-level factors were identified from published systematic reviews about psychoeducational interventions (Lobban, Postlethwaite, et al., 2013; NICE, 2010; Sin & Norman, 2013; Sin et al., 2015; Xia et al., 2011), and were derived from theories or conceptual frameworks underpinning these interventions.

#### 3. Results

The database search resulted in 8141 records; of these 48 papers of 32 studies met all inclusion criteria and were included in this review (See Fig. 1 for the PRISMA flowchart and Table 1 for a summary of included studies). In reporting the results below, studies are referred to according to the numbering in Table 1. Twenty-one RCTs (studies 1–5, 10–12, 14–19, 23, 26, 27, 29–32) published between 1987 and 2011, were identified in our earlier review where results were synthesised using a narrative approach without meta-analysis (Sin & Norman, 2013). This update added 11 studies (reported in 13 papers) published since 2012 (studies 6–9, 13, 20–22, 24, 25, 28). Altogether, the 32 studies included 2858 family carers and 1305 patients from 15 (out of 32, 47%) studies where patients also participated in (part of) the

interventions. These studies were undertaken in the following countries: China [k=10, eight published in English (studies 2–7, 18, 31); two in Chinese (studies 17, 19)]; North America [k=4 (studies 11, 26, 27, 30)]; Europe [k=4 (studies 1, 10, 21, 23)]; U.K. [k=4 (studies 16, 20, 30, 32)]; Middle East [k=6 (studies 9, 13, 14, 24, 25, 28)]; South America [k=1 (study 12)]; Australia [k=1 (studies 8, 22)]; and India [k=1 (study 15)].

#### 3.1. Overview of interventions, settings and family carer-participants

Most studies included carers of patients living in the community, excluding four trials which recruited carers of patients while they were receiving treatment in hospital (studies 9, 11, 18, 25). Five studies recruited carers of patients who experienced psychosis for the first time, and were under the care of Early Intervention in Psychosis Service (EIPS) (studies 7, 16, 20, 22, 31). The remainder targeted carers of individuals with a long term psychotic disorder, most commonly schizophrenia. In 75% of studies (k = 24), and where the relationships between the carers and patients were reported, parents, especially mothers, made up the majority of participants in 21 studies, and indeed were the only kind of family carers in three studies (studies 14, 29, 31).

In terms of delivery formats, most interventions used the conventional face-to-face medium: three studies evaluated individual (carer or family as units) programmes (studies 11, 16, 25); 19 used groups where carers from different families undertook the programmes together (studies 1–6, 9, 10, 12, 14, 15, 21, 23, 24, 26, 28–31); and four used a combination of individual and group sessions (studies 17–19, 32). Several studies included telephone- (studies 8, 13, 22) and/or email-support (study 20) to supplement text-based psychoeducational interventions; one also included face-to-face group sessions, in addition to telephone-supported bibliotherapy-based intervention (study 7). One RCT evaluated a web-based psychoeducation programme which was provided to both patients and their carers (study 27).

All studies were randomised at the level of the individual, bar one (study 18) which was a cluster trial based on wards. Most trials compared psychoeducation with treatment as usual/standard care, or an attention-control comparator. Two studies employed a three-arm RCT design, comparing a psychoeducation group with a mutual support group and standard care (studies 4, 6). One study compared a psychoeducation group with individual counselling for carers (study 29), and another compared psychoeducation group with postal information (study 30).

#### 3.2. Quality of included studies

Our overall evaluation of the risk of bias of included RCTs is presented in Supplementary Figs. 1 and 2. Sequence generation was adequately described in 12 studies, unclear in 18, and regarded as high risk in two given somewhat contradictory accounts of randomisation process. Thirteen studies were rated as low risk in terms of allocation concealment, 19 as unclear. Masking of participants and trial therapists was not possible in all studies; a common challenge in psychological intervention research. Therefore we rated all studies as moderate risk as such. For masking of outcome assessment, we rated 14 studies as low risk, 17 unclear, and one high risk. Regarding incomplete outcome data due to attrition or missing data, 15 studies were at low risk of bias, 10 unclear, and seven high. Approximately one-third of studies had published protocols or trial registration forms, and so we were able to confirm that outcomes were reported in 12 studies as planned. However, 11 studies were rated as unclear risk and nine high risk of selective outcome reporting. Overall, carers' outcomes were often not reported as primary outcomes even in those trials in which only carers participated; patients' outcomes, such as mental state and relapse rates, took primacy. Carers' outcomes were measured in a variety of ways using different scales and follow up data beyond the end of the intervention were sparse. We considered that these factors incurred

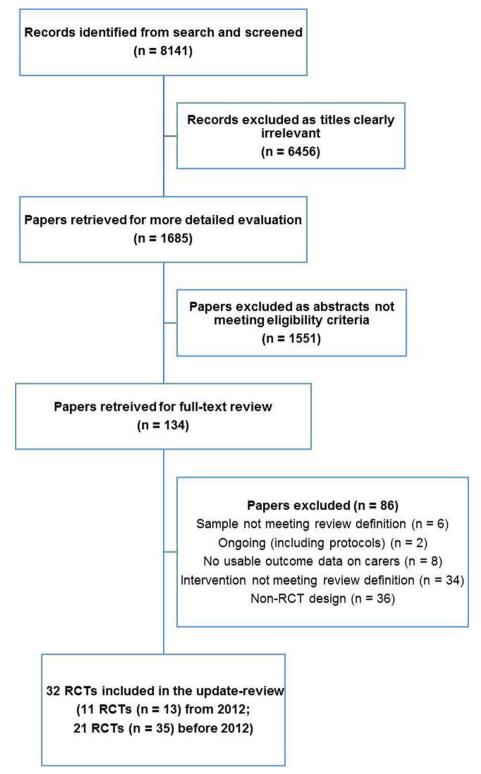


Fig. 1. PRISMA flowchart.

other biases which were subsequently rated as either unclear or high risk in 20 studies.

#### 3.3. Primary outcomes: carers' wellbeing, quality of life and proxy measures

Two studies (8, 20), including 184 carers, examined the effectiveness of psychoeducational interventions, delivered via booklets and augmented with weekly telephone and/or email support, for carers. Results were equivocal when comparing these interventions with

inactive controls, at post-intervention respectively (2 RCTs,  $n=184, \, SMD \, 0.103, \, 95\% \, CI \, -0.186$  to  $0.392, \, I^2=0\%$ ). Only one study (13) measured carers' quality of life as an outcome when comparing psychoeducation with usual care. Study findings indicated no significant differences between groups (1 RCT,  $n=121, \, SMD \, 0.145, \, 95\% \, CI \, -0.205$  to 0.495). See Fig. 2 for meta-analysis on the primary outcomes.

In terms of proxy measures of carers' wellbeing, we examined carers' stress, global morbidities, and depression. The analysis of stress

(continued on next page)

 Table 1

 Characteristics of included studies.

Study no.	Study author(s) <sup>3</sup> and year published	Country	Sample size of carers (patient if included)	Psychoeducation	Comparator	Gender of carer (female - %)	Mean age of carer (years)	Follow up
				<ul><li>Format</li><li>Contact time (hours)/duration (weeks)</li></ul>				
1	Carra, Montomoli, Clerici, & Cazzullo, 2007	Italy	101	Groups	TAU	65	NR	12, 24 months
2	Chan, Yip, Tso, Cheng, & Tam, 2009	Hong Kong	73 (73)	Groups 20 h / 12 weeks	Waitlist	Majority female	NR	6, 12 months
ю	Cheng & Chan, 2005	Hong Kong	64	Groups	TAU	63%	NR	No FU
4	Chien, Chan, & Thompson, 2006 <sup>b</sup> ; Chien & Chan, 2004; Chien, Chan, Morrissey, & Thompson, 2005	Hong Kong	(96) 96	20 II/12 weeks Groups 24 h/26 weeks	TAU Mutual support	31%	42	6, 12, 18 months
S	Chien & Wong, 2007	Hong Kong	84 (84)	Groups	group TAU	67%	41	12 months
9	Chien & Thompson, 2013 <sup>b</sup> ; Chien & Chan, 2013	Hong Kong	135 (135)	30 II/30 weeks Groups 28 h/40 weeks	TAU Mutual support	38%	42	12, 24 months
7	Chien, Yip, Liu, & McMaster, 2016 <sup>b</sup> ; Chien, Thompson, Lubman, & McCann, 2016	Hong Kong	116	Text-based with telephone support and group sessions	group TAU	92%	20	6, 12 months
8	Deane, Marshall, Crowe, White, & Kavanagh, 2015	Australia	80	Text-based with telephone support 24 h/52 weeks	Information booklet	%88%	54	No FU
6	Fallahi Khoshknab, Sheikhona, Rahgouy, Rahgozar, & Sodagari, 2014	Iran	71	Groups 8 h/5 weeks	TAU	93%	54	1 month
10	Fiorillo, Bassi, de Girolamo, Catapano, & Romeo, 2011	Italy	230 (212)	Groups	TAU	65%	29	No FU
11	Glick, Clarkin, et al., 1990", Glick, Spencer, et al., 1990", Glick, Clarkin, Haas, Spencer, & Chen, 1991; Clarkin, Glick, Haas, & Spencer, 1991; Haas, Glick, Clarkin, & Spencer, 1988; Haas, Glick, Clarkin, Spencer, & Lewis, 1900. Spencer et al. 1988	USA	92 (92)	Individual family sessions 6 h/10 weeks	TAU	NR	NR	6, 18 months
12	Maldonado, & Canneo-Urizar, & Ferrer-Garcia, 2009 <sup>b</sup> ; Gutierrez-Maldonado, Caqueo-Urizar, Anglonado, & Canneo-Urizar, 2007	Chile	45	Groups	TAU	76%	54	No FU
13	Hasan, Callaghan, & Lymn, 2015	Jordan	121 (121)	Text-based with telephone support	TAU	76%	48	3 months
14	Koolaee & Etemadi, 2010	Iran	62	140 II/12 weeks Groups 24 h/14 weeks	TAU Behavioural family	100% mothers	55	3, 6 months
15	Kulhara, Chakrabarti, Avasthi, Sharma, & Sharma, 2009	India	76 (76)	Individual family sessions	TAU	25%	47	No FU
16	Leavey et al., 2004	UK	106	9 h/40 weeks Individual carer sessions	TAU	NR	NR	5 months
17	Li & Xu, 2003	China	139 (120)	7 h/18 weeks Individual family sessions	TAU	NR	NR	No FU
18	Li & Arthur, 2005	China	101 (101)	6 h/26 weeks Individual family sessions 42 h/18 weeks	TAU	NR	NR	6 months
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Table	

Study no.	Study author(s) <sup>a</sup> and year published	Country	Sample size of carers	Psychoeducation	Comparator	Gender of carer	Mean age of	Follow up
			(patient if included)	<ul><li>Format</li><li>Contact time (hours)/duration (weeks)</li></ul>		(female - %)	carer (years)	
19	Liu, Gao, Yue, Zhan, & Liu, 2004	China	118 (118)	Individual family sessions and groups	TAU	NR	NR	No FU
20	Lobban, Glentworth, et al., 2013; Lobban, Postlethwaite, et al., 2013	UK	103	13 h/52 weeks Text-based with telephone/email support Unspecified <sup>d</sup> /	TAU	82%	NR	No FU
21	Martin-Carrasco et al., 2016	Spain & Portugal	223	26 weeks Groups	TAU	76%	09	4 months
22	McCann et al., 2013	Australia	124	21 h/12 weeks Text-based with telephone support	TAU	82%	47	2 months
23	Merinder et al., 1999 <sup>b</sup> , Merinder et al., 1998a, 1998b, Merinder, 2000	Denmark	46 (46)	10 h/5 weeks Groups	TAU	NR	NR	12 months
24	Navidian, Kermansaravi, & Rigi, 2012	Iran	50°	Groups	TAU	NR	NR	3 months
25	Ozkan, Erdem, Ozsoy, & Zararsiz, 2013	Turkey	62	s n/5 weeks Individual sessions with telephone support	Waitlist	53%	NR	6 months
26	Posner, Wilson, Kral, Lander, & McIlwraith, 1992	Canada	55	6 h/30 weeks Groups	Waitlist	NR	NR	6 months
27	Rotondi et al., 2005 <sup>b</sup> ; Rotondi et al., 2010	USA	21 (31)	12 h/9 weeks Web-based multi-	TAU	NR	NR	6, 12 months
				programme Unspecified <sup>d</sup> /				
28	Sharif, Shaygan, & Mani, 2012	Iran	70	Groups	TAU	Majority were	51	1 month
29	Shin, 2004	USA	48	Groups	Individual carer	65%	99	No FU
30	Smith & Birchwood, 1987	UK	40	Groups	Information booklet	NR	NR	6 months
31	So et al., 2006	Hong Kong	45	6 n/4 weeks Groups	Waitlist	78%	49	6 months
32	Szmukler et al., 2003	UK	61	9 n/o weeks Mixed individual and group carer sessions 24 h/40 weeks	1 h individual carer session	82%	24	6 months

TAU = treatment as usual, NR = not report.

<sup>a</sup> Additional author names are cited to differentiate publications if necessary.

<sup>b</sup> Denotes the major publication for the study.

<sup>c</sup> Only data on 50 carers of patients diagnosed with schizophrenia out of the total 100 carers were extracted for the review.

<sup>d</sup> No contact hours specified as carers were encouraged to use the resource as much as they wish.

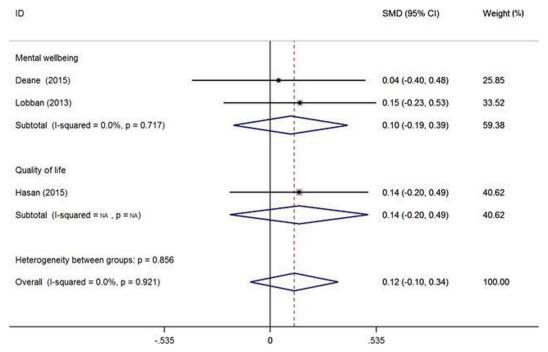


Fig. 2. Meta-analysis on carers' wellbeing and quality of life.

included four studies. Three studies compared telephone-supported bibliotherapy-based psychoeducation (studies 8, 22), or web-based multi-component psychoeducation (study 27) with inactive controls; results showed no significant differences between groups (3 RCTs, n = 226, SMD - 0.133, 95% CI - 0.394 to 0.128,  $I^2 = 0\%$ ). One study (30) compared psychoeducational groups with postal booklets as an active control (1 RCT, n = 40). When combined, the overall analysis indicated no significant differences in stress levels across psychoeducation and comparator groups (4 RCTs, n = 266, SMD -0.169, 95% CI -0.410 to 0.072,  $I^2 = 0\%$ ). Regarding global morbidities, seven studies provided data about a range of physiological and emotional morbidity outcomes. Psychoeducation yielded a small but significant effect when compared to inactive controls (6 RCTs, n = 616, SMD -0.22, 95% CI -0.386 to -0.065, I<sup>2</sup> = 37.5%) (studies 12, 17, 20-22, 26). Only one study (30) compared psychoeducation to postal booklets (1 RCT, n = 40). The meta-analysis including these seven studies showed an overall significant effect of psychoeducation compared to controls in reducing global morbidities (7 RCTs, n = 656, SMD -0.230, 95% CI -0.386 to -0.075,  $I^2 = 25.6\%$ ). Two studies (21, 25) examined the impact of psychoeducation on depression; and psychoeducation showed a significant positive effect over inactive controls (2 RCTs, n = 245, SMD -0.70, 95% CI -0.97 to -0.44,  $I^2 = 97.2\%$ ). Of note, heterogeneity of these two studies was high: one was a European study examining psychoeducation groups for carers (study 21); and one investigated psychoeducation delivered to carers individually in the Middle East (study 25). See Fig. 3 for meta-analysis on proxy measures of carers' wellbeing.

#### 3.4. Secondary outcomes: caregiving-related outcomes

Five studies (7, 8, 20, 22, 31) examined positive and negative aspects of caregiving in carers. While psychoeducation did not yield significantly different results for enhancing carers' positive caregiving experiences, compared with inactive controls (5 RCTs, n = 452, SMD 0.032, 05% CI -0.151 to 0.216,  $I^2=0\%$ ), there was some suggestion that negative appraisals were improved (5 RCTs, n = 446, SMD -0.21, 95% CI -0.396 to -0.025,  $I^2=0\%$ ).

Considering caregiving-related burden, the meta-analysis, including 10 studies with 878 participants (studies 2, 3, 5, 7, 9, 13, 21, 24, 25, 28)

showed a significantly superior effect of psychoeducation to inactive controls in reducing carers' perceived burden (10 RCTs, n=878, SMD -0.434, 95% CI -0.567 to -0.301,  $I^2=0\%$ ).

Analysis of carers' expressed emotion (5 RCTs, n = 337, SMD -0.161, 95% CI -0.367 to 0.045,  $I^2 = 0\%$ ) (studies 1, 22, 23, 25, 31), family functioning (3 RCTs, n = 238, SMD 0.135, 95% CI - 0.120to 0.391,  $I^2 = 0\%$ ) (studies 4–6), and perceived social support (4 RCTs. n = 303, SMD 0.133, 95% CI - 0.093 to 0.360,  $I^2 = 0\%$ ) (studies 2, 4, 6, 15), revealed no significant differences between psychoeducational interventions and inactive controls. Nonetheless, psychoeducation showed a significantly improved effect compared to inactive controls, in improving carers' knowledge in psychosis (4 RCTs, n = 310, SMD 0.361, 95% CI 0.136 to 0.586,  $I^2 = 49.8\%$ ) (studies 8, 13, 18, 26). The heterogeneity of these studies was bordering on high. The four studies concerned were undertaken in Australia (study 8), the Middle East (study 13), China (study 18), and Canada (study 26), and each investigated a different modality of psychoeducation, in which the duration ranged from 9 to 52 weeks. See Table 2 for meta-analyses on all a priori outlined secondary outcomes.

#### 3.5. Follow up outcome data

Follow up data beyond the post-intervention period were sparse, limiting the meta-analysis to largely secondary outcomes, all of which compared psychoeducation with inactive controls. At 6-month postintervention, no data were available on carers' wellbeing or quality of life; and only one study provided data on proxy measures such as global morbidities (study 26) or depression (study 25). Indeed, meta-analysis was only feasible on one secondary outcome, that is, carers' perceived burden, which had data available from 10 studies (10 RCTs, n = 821, SMD -1.628, 95% CI -2.307 to -0.948,  $I^2 = 94.5\%$ ) (studies 2, 4, 7, 9, 13, 14, 21, 24, 25, 28). The analysis suggested that the superior effects of psychoeducation on reducing carers' burden seem to sustain up to 6-month post-intervention. At 12-month post-intervention, no data were available for any of our primary outcomes. Three studies reported carers' perceived burden (studies 2, 5, 7); the analysis identified no significant differences between psychoeducation and inactive controls at one year follow up (3 RCTs, n = 269, SMD -0.024, 95% CI -0.279 to 0.230,  $I^2 = 96.7\%$ ). Analysis on family

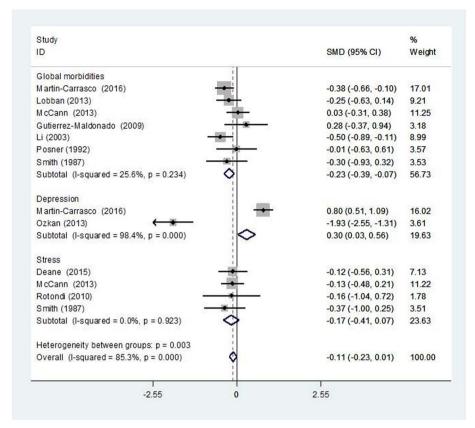


Fig. 3. Meta-analysis on proxy measures of carers' wellbeing.

functioning (2 RCTs, n = 174, SMD 0.663, 95% CI -0.382 to 1.707,  $I^2=0\%$ ) and on carers' perceived social support (2 RCTs, n = 163, SMD 0.255, 95% CI -0.053 to 0.563,  $I^2=0\%$ ) showed no significant differences between psychoeducation and inactive control groups (studies 2, 6). Data for over 12-month follow up were limited and precluded any meta-analysis on both primary and secondary outcomes.

#### 3.6. Meta-regression on intervention factors and treatment effect

Intervention duration ranged from four to 52 weeks, mean duration across 32 trials was 20 weeks (median = 16 weeks). Intervention contact times ranged from six to 42 h, with a mean of 17.4 h (median = 15.5 h). Meta-regression investigating the differential effects, if any, of the intervention contact times (in terms of hours), intervention duration (in terms of weeks), and modes of delivery (group or individual) could only be conducted for the outcome of carers' perceived burden. All other analyses on outcomes included data from

less than eight studies. There was no association between intervention contact time and effect size of carers' perceived burden (regression coefficient 0.006, 95% CI - 0.038 to 0.051, p = 0.732). A similar lack of relationship between intervention duration and intervention effects on carers' perceived burden was also observed (regression coefficient  $0.020,\ 95\%\ CI\ -0.021$  to  $0.061,\ p=0.266$ ). Meta-regression on interventions delivered using group formats or otherwise was highly imbalanced, as group programmes significantly outnumbered other modalities. For instance, for the 10 studies that provided usable data for the meta-analysis on carers' perceived burden, eight reported group programmes which included multiple carers in face-to-face sessions (studies 2, 3, 5, 7, 9, 21, 24, 28); and two used an individual format with the patient-carer pairs as a family unit (studies 13, 25). Nevertheless, the analysis showed no significant relationships between outcome effect and mode of delivery using either format (regression coefficient 0.095, 95% CI -0.293 to 0.483, p = 0.588).

Table 2
Overview of meta-analyses on secondary outcome measures.

Outcome measures	Studies (k)	Sample (N (n/n)) <sup>a</sup>	SMD	95% CI	p Value	I <sup>2</sup> (%)
Positive caregiving experience	5	452 (224/228)	0.032	- 0.151 to 0.216	0.729	0
Negative caregiving experience	5	446 (220/226)	-0.210	-0.396 to $-0.025$	0.026	0
Perceived burden	10	878 (445/433)	- 0.434	-0.567 to $-0.301$	< 0.001	0
Coping	2	151 (75/76)	-0.178	- 0.500 to 0.144	0.278	82.6
Self-efficacy	2	137 (68/69)	0.187	- 0.148 to 0.522	0.274	0
Expressed emotion	5	337 (155/182)	-0.171	- 0.377 to 0.035	0.104	0
Family functioning	3	238 (120/118)	0.135	-0.120 to 0.391	0.299	0
Perceived social support	5	393 (197/196)	0.103	- 0.096 to 0.301	0.310	0
Knowledge	4	300 (154/156)	0.361	0.136 to 0.586	0.002	49.8
Норе	2	184 (92/92)	0.032	- 0.257 to 0.321	0.826	0
Satisfaction with support	4	264 (131/133)	0.238	- 0.004 to 0.480	0.054	0

<sup>&</sup>lt;sup>a</sup> Total number of carer-participants included in the analysis (number of carer-participants in psychoeducation groups/number of carer-participants in comparator groups), bold print denotes significant effect.

#### 4. Discussion

The aim of this review was to quantitatively synthesise data obtained from RCTs about the effectiveness of psychoeducation for improving psychosis carers' wellbeing, quality of life and caregivingrelated outcomes. Thirty-two RCTs, providing data on 2858 carers, were included in the review. Importantly although carers participated in all interventions, not all of them reported carers' outcomes (6 studies (19%) provided no usable carer outcome data which could be included in the meta-analysis), let alone carers' wellbeing, quality of life or proxy measures as an individual. At post-intervention, only two studies provided data on carers' wellbeing and one on carers' quality of life. Psychoeducation showed a significant albeit small effect, compared with usual care or inactive comparators in ameliorating carers' global morbidities, as a proxy measure of carers' wellbeing. Relatively more data were available on caregiving-related outcomes. Results showed an overall significant small effect of psychoeducation on carers' negative appraisal of caregiving experiences, perceived burden, and knowledge about psychosis and illness-related management. The available data limited our planned meta-regression on intervention factors and carers' outcomes. Nonetheless, it is worth noting that the majority of interventions included a group-element which enabled carers to exchange experiences and support with their peers, and intervention duration and contact times varied between studies. Follow-up data were lacking, limiting the extent of meta-analysis on any carers' longer term outcomes.

There is currently no evidence existing from the few studies indicating any associations between the pre-specified intervention factors (duration, contact time and using a group format or otherwise) and effect on carers' outcomes. It is possible, however that the analyses lacked power to detect significant differences. Interventions solely delivered via face-to-face group meetings were most commonly used (k = 19, 59%), and when calculating the number of interventions that incorporated a group element, a further 6 studies were included (78% of all included studies). It may be that the opportunity to share personal experiences with peers, and learn from others' experiences, serves to reduce isolation, normalising the experiences and enhance self-efficacy (Gillard et al., 2015; Sin & Norman, 2013).

Despite the growing popularity of eHealth and mHealth interventions (Chi & Demiris, 2015; Cucciare & Weingardt, 2010; Powell & Clarke, 2006), only one study (Rotondi et al., 2005; Rotondi et al., 2010) included here (and one protocol of a study yet to be published by Sin, Henderson, Pinfold, & Norman, 2013) described a fully web-based intervention delivered to both the carers and the cared-for persons. Web-based interventions are advantageous because participants can decide which components or strategies resonate with them, how much to spend accessing the site, and when to do so (Chi & Demiris, 2015; Sin, 2013; Sin et al., 2014). The early indications are that recruitment and retention rates are comparable between face-to-face and online interventions. However, compared to interventions for carers of individuals with dementia (Chi & Demiris, 2015; Powell, Chiu, & Eysenbach, 2008) or eating disorders (Grover et al., 2011; Hoyle, Slater, Williams, Schmidt, & Wade, 2013), we have some way to go to ensure that e and mHealth interventions for carers of people with psychosis incorporate and integrate evolving technologies to enhance accessibility and flexibility (Powell et al., 2013; Sin et al., 2014; Webb, Joseph, Yardley, & Michie, 2010).

#### 4.1. Strengths, limitations and recommendations

Building upon previous reviews (Sin & Norman, 2013; Sin et al., 2015), we have been able to synthesise data from 32 RCTs and produce meta-analyses focusing on carers' outcomes. Furthermore, this review has yielded new data about mixed-modality interventions, and facilitated comparisons of the effectiveness of these interventions compared with active and inactive controls. While the wide range of interventions, undertaken across geographical regions may have contributed to

heterogeneity in the planned analyses, this may also have enhanced generalisability of the review findings. Fewer than half of the included studies (k=14) were undertaken in English-speaking or western cultures, while one-third were conducted in China (k=10) and the rest in the Middle East, South America and South-East Asia (k=8). This evidence may suggest that psychoeducational interventions are popular and widely adaptable in different clinical settings world-wide, and that psychoeducation for carers could be beneficial for those caring for a loved one across the diverse range of psychotic disorders, from first episode psychosis to long-term schizophrenia.

As culture has a significant role in how mental (ill) health is understood and treated, the process and meaning of family caregiving for a loved one with psychosis is also likely to be interpreted differently across ethnic-cultural context (Earl, 2007; Sin et al., 2012). For instance, it is much more common for the patients to live under the same roof with their family carers in the Chinese culture. In fact, all the Chinese studies (e.g. Chan et al., 2009; Chien et al., 2005; Li & Arthur, 2005) stipulated that carers and patients had to live together, as one of the eligibility criteria. These ethnic-cultural factors are likely to influence the caregiving roles, activities, and the carer's outcomes. With the growing interest for research and clinical development in family psychoeducation globally, we expect to see further studies coming out from both Western and non-Western cultures in the near future. Richer study data should allow further exploration into intervention effectiveness and any moderating mechanisms considering the ethnic-cultural factors.

We acknowledge several limitations to this review. First, the available data underpinning our primary and secondary outcomes were limited. Similarly, follow-up data were sparse, limiting analyses on outcomes beyond post-intervention time point to nearly non-existent. Results of meta-analyses should be interpreted with caution due to a high risk of inadequate power when data were only available from a small number of studies. While the published literature was comprehensively searched and carer outcome data meticulously extracted for this review, there remains a possibility of publication bias in that studies with null results for patients and/or carers are in the "file drawer" and never published (Miyar & Adams, 2013; Higgins & Green, 2011). If such publication bias, in fact, exists, it may imply that the results presented in this review may have overstated the direct benefits of family psychoeducational interventions to carers. Second, we took the approach to report all secondary outcomes which were outlined a priori (Sin et al., 2016). In the event, the secondary outcomes related to caregiving experiences were more frequently reported by included studies. However, some of the meta-analyses of the secondary outcomes also reflected significant heterogeneity (likely both clinical and methodological) and a lack of precision. Third, although carers were (sometimes the only) recipients of the psychoeducational interventions, their outcomes and characteristics were often poorly or not reported by the studies. This not only limited the data on carers' outcomes, but also impeded our understanding of the carers' demographic characteristics, and hence any possible differential response to the intervention based on carers' characteristics. Fourth, our meta-analyses focused on carer's outcomes solely without exploring any possible associations between carer's and patient's outcomes. Hence it is possible that patient's improved clinical status might have contributed, in part, to carer's improved outcomes (such as perceived burden). Fifth and lastly, it is worth-noting that the quality of some of the included studies, in particular their reporting of randomisation sequence generation, allocation concealment, blinding, and reporting bias, were considered as high risk of bias. The quality of the evidence of some of the results should be interpreted in light of the risk of bias assessment of the data

We suggest several key priorities for future research. It is evident that although carers have been offered psychoeducational interventions, outcomes are often not reported for this group of participants, a situation which should not be repeated in future studies. With the increasing recognition of carers' right and contribution to their loved one's care, we expect studies targeting carers (with or without the patients) to gain significance in funded research priorities (NICE, 2010; Kuipers, 2010). We propose that carers' outcomes could constitute primary study outcomes (i.e. acknowledging carers in their own right), or it may be that studies are designed to measure dual primary outcomes (i.e. for patients and for carers). Further systematic reviews could then take advantage of such data to explore any correlation between patient's and carer's outcomes. More evidence is needed to establish which modalities are associated with improved outcomes, and whether there is an optimal duration and contact time. Additionally, we suggest that outcomes are measured at distinct time points, at medium and long-term follow-up periods as it may take participants some time to be able to implement strategies consistently. We also recommend that carers' wellbeing and proxy measures are evaluated using standardised questionnaires and scales (Miyar & Adams, 2013). This will help facilitate understanding of the relational process between carers' wellbeing and their caregiving capacity. Essentially, and, in turn, how these carers' outcomes correlate to patients' outcomes like decreased relapse and better compliance, and to family-wide outcomes like family relationship and communication, and vice versa, needs to be better explored. Lastly as is good practice we would encourage study authors to report data according to CONSORT guidelines (Schulz, Altman, Moher, & The CONSORT Group, 2010).

#### 5. Conclusion

The review findings indicate that psychoeducation is beneficial for enhancing carers' knowledge about mental health, appraisal about caregiving, perception of burden, and emotional support. Better understanding of treatment mediators and moderators may inform optimal design of psychoeducational interventions, targeting both patients' and carers' outcomes. Additionally, while improving caregiving capacity is of pivotal importance for patients' outcomes, carers' needs in terms of their own health and wellbeing should be better understood, and subsequently, addressed.

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Statement 2: Contributions of authors

Jacqueline Sin: conception and design of the protocol, search, screening and assessment of studies, data extraction, quality assessment, analysis and interpretation of data, writing and reviewing the paper.

Steve Gillard: protocol design, supervision of the review, writing and reviewing the paper.

Debbie Spain: protocol design, screening of search results, data extraction, quality assessment, writing and reviewing the final paper.

Victoria Cornelius: protocol design, analysis and interpretation of data, writing and reviewing the final paper.

Tao Chen: protocol design, analysis and interpretation of data, writing

and reviewing the final paper.

Claire Henderson: protocol design, supervision of the review, writing and reviewing the paper.

All authors contributed to and have approved the final manuscript. Statement 3: Conflict of interest

All authors declare no conflict of interest.

#### Appendix A. Supplementary data

Supplementary data to this article can be found online at http://dx.doi.org/10.1016/j.cpr.2017.05.002.

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