Psychosocial interventions for carers of persons with schizophrenia/psychosis/schizophrenia spectrum disorder, bipolar disorder or substance use disorder

WHO mhGAP guideline update: Mental Health Gap Action Programme (mhGAP) guideline for mental, neurological and substance use disorders

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Contents

Mental Health Gap Action Programme (mhGAP) guideline for mental, neurological and substance use disorders, available at: https://www.who.int/publications/i/item/9789240084278

1. Background

This systematic review aimed to explore whether psychosocial interventions (i.e. psychoeducation, cognitive-behavioural therapy, counselling, self-help groups) for carers of persons with schizophrenia/psychosis/schizophrenia spectrum disorder, bipolar disorder or substance use disorder produce benefit/harm with respect to a series of specified outcomes as compared to placebo/other controls.

2. Methodology

2.1. PICO question

Population (P): Carers of people with psychoses or alcohol and drug use disorders
Intervention (I): Psychoeducation, cognitive-behavioural therapy, counselling, self-help groups
Comparator (C): Placebo/comparator
Outcomes (O):

Critical outcomes:

- burden (subjective/objective), depressive symptoms, well-being/quality of life

Important outcomes:

- sleep, skills/knowledge, self-efficacy, chronic stress (e.g. measured by cortisol levels), physical health

2.2. Search strategy

The search strategy has included the following key words: “psychosocial intervention(s)”, “psychoeducation”, “cognitive-behavioural intervention(s)”, “psychoeducational intervention(s)”, “counselling”, “self-help”, “family member(s)”, “carer(s)”, “caregiver(s)”, “sibling(s)”, “parent(s)”, “relative(s)”, “spouse”, “mental disorder(s)”, “schizophrenia”, “psychosis”, “alcohol use disorder(s)”, “drug use disorder(s)”. The key words were entered in the following sources: PubMed/MEDLINE, Embase, PsycInfo, Cochrane Central Register of Controlled Trials (CENTRAL), CINAHIL, Scopus, African Index Medicus, Index Medicus for the Eastern Mediterranean Region, Index Medicus for the South-East Asian Region, Latin American and Caribbean Health Sciences Literature, and Western Pacific Region Index Medicus. Furthermore, repositories of systematic review protocols, including PROSPERO, Open Science Framework (OSF) and Cochrane were searched using the same key words. Only articles written in English were included. The review by Yesufu-Udechuku et al. entitled “Interventions to improve the experience of caring for people with severe mental illness: systematic review and meta-analysis” and published in the British Journal of Psychiatry (206:268-274) in 2015 was identified.
The AMSTAR quality appraisal tool was used to assess the quality of the identified systematic review (https://amstar.ca/Amstar_Checklist.php). The evaluation report is attached. The quality of the selected review was found to be very good and the PICO to be fully addressed by it. However, studies included in this systematic review and all further studies identified using the above mentioned strategies, have been included.

2.3. Data collection and analysis

For the purposes of study selection, carers were defined as relatives or friends who provide informal and regular care/support to someone with severe mental illness. Interventions were included if they were provided to the carer and if they aimed to improve the carer’s experience in terms of personal burden (subjective/objective), quality of life, depressive symptoms and/or well-being.

Other secondary outcomes considered were sleep, skills/knowledge, self-efficacy, chronic stress (e.g. measured by cortisol levels), and physical health. Only studies targeting carers of persons with schizophrenia/psychosis/schizophrenia spectrum disorder, or bipolar disorder, or substance (alcohol and/or drugs) use disorder were included.

We excluded studies on interventions targeting the patient rather than the carer, and those focused on persons affected by other mental disorders.

2.4. Selection and coding of identified records

For each selected study, the design, the sample and intervention characteristics, and the results were extracted independently by two researchers.

2.5. Quality assessment

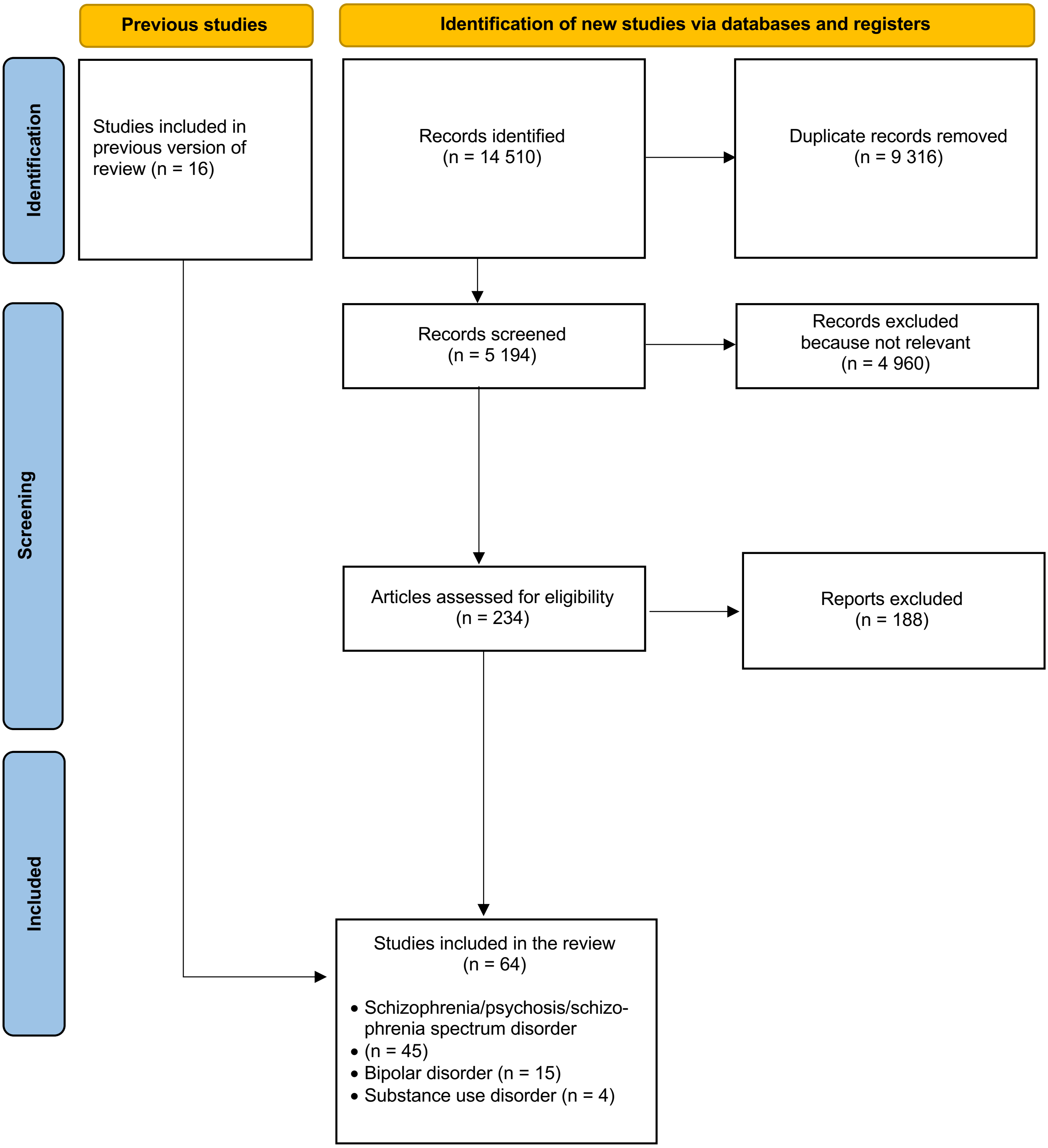
The quality and level of evidence of each study were independently assessed by two researchers using the GRADE criteria for quantitative studies, and the Critical Appraisal Skills Programme (CASP) tool for qualitative research. The authors independently assessed the studies against these criteria and resolved discrepancies through discussion.

3. Results

3.1. Systematic reviews and/or studies identified by the search process

An overview of the study identification process is provided in Figure 1. Overall, 14 510 studies were retrieved from the electronic search; of these, 9 316 were duplicates and were subsequently excluded. Of the remaining 5 194 studies, 234 full-text articles were analysed for potential inclusion in the review. Based on previous review, 16 additional papers were added. 64 studies were finally included.

Fig. 1. PRISMA flow diagram. One study included carers of persons with either psychosis or bipolar disorder, while one study included carers of persons with either bipolar disorder or substance use disorder.



3.1.1. Included in GRADE tables/footnotes

See Appendix I for a full list of included studies.

3.1.2. Excluded from GRADE tables/footnotes

No eligible studies were excluded from the systematic review.

3.1.3. Description of interventions

Brief Cognitive Behavioural Stress Management Programme

The Brief Cognitive Behavioural Stress Management Programme is a semi-structured programme that was devised to allow the caregiver to gain awareness of various aspects of his or her daily life and distress due to caregiving responsibilities, as well as to assist the caregiver in developing stress management skills in a practical group environment. In this programme, several aspects of other stress management programmes, cognitive-behavioural therapy techniques, and resources for group psychotherapy are used. The approach has been manualized and consists of seven sessions.

Collective Narrative Therapy

Collective Narrative Therapy is a narrative group intervention, consisting of eight group sessions with different goals. All groups are facilitated by the same practitioner. The main topics are: creating relationship; describe, externalize and evaluate problems; understand and solve problems; reflect and make sense of experiences, and share positive communication; relax body and mind, and explore the meaning of life and inner strengths; and rewrite life stories and ascertain life goals.

Psychoeducation

Psychoeducation is defined as a psychosocial intervention with systematic and structured knowledge transfer about an illness and its treatment, integrating emotional and motivational aspects to enable carers to cope with the illness and to improve patients' treatment adherence. The content of psychoeducation interventions includes etiology of illness, treatment process, adverse effects of prescribed medications, coping strategies, coping skills training, problem solving training.

Family-Focused Culturally-Informed Treatment model

The Family-Focused Culturally-Informed Treatment model is an individual or couple treatment for caregivers of persons with bipolar disorder. It is based on three premises supported by extensive research and theory: a) negative and dysfunctional automatic thoughts, feelings and core beliefs about caregiving contribute to and sustain depressive symptoms and perceived burden among caregivers; b) depressive symptoms interfere with caregiver self-care and ability to manage the demands and stress associated with caregiving; c) the presence of caregiver's depressive symptoms interferes with management of caregiving demands and impacts on severity of patient's mood symptoms.

Family-Led Mutual Support Group programme

The Family-Led Mutual Support Group programme consists of 16 bi-weekly 2hr sessions co-led by two peer family caregivers. These caregivers are relatively more experienced in caregiving and are trained by the researchers to perform the peer leader role with a three full-day psychoeducation and supportive skills workshop. The workshop's contents are structured in five stages, including engagement; awareness and addressing mutually shared psychosocial needs; managing common and individual physical and psychosocial needs of self and family members; taking up caregiving roles and demands and facing with challenges; group termination.

All sessions place emphasis on supportive sharing of experience and information exchanges, problem-solving and caregiving skill practices.

Yoga/Self-Help intervention

This consists of a selfhelp manual and DVD for practicing yoga intended for caregivers of patients with schizophrenia.

Supportive-Educational interventions

Supportive-Educational interventions consist of sessions aiming to improve levels of knowledge about the disorder, how to handle difficult behaviours, stress management, communication skills, and relapse prevention.

Online intervention (“mi.spot”)

“mi.spot” is an online, manualized intervention that targets young adults who have a parent with a mental illness and/or substance use disorder. The topics include: introduction to the intervention; information about mental disorders; assessing relationship with parents and/or other family members; managing stress; discussion on caring responsibilities; taking control of own life.

3.2. Narrative description of studies that contributed to GRADE analysis

Interventions for carers of persons with schizophrenia/psychosis/schizophrenia spectrum disorder were conducted in 18 different countries, the most represented being Hong-Kong (n = 8), Australia (n = 7), India (n = 5), and United Kingdom (n = 4). Interventions for carers of persons with bipolar disorder were conducted in 12 different countries, the most represented being Italy (n = 3), Spain (n = 2), Australia (n = 2), and the US (n = 2). For carers of persons with substance use disorder, two out of the four included studies were carried out in Iran.

The most frequently adopted study design (n = 48 studies; 72.7%) was randomized controlled trial (RCT). In particular, RCT was used in 34 (72.3%) studies on carers of persons with schizophrenia/psychosis/schizophrenia spectrum disorder, in 12 (80%) studies on carers of persons with bipolar disorder, and in two (50%) studies on carers of persons with substance use disorder.

Psychoeducation was the most frequently used intervention. In particular, it was included in 38 studies on carers of persons with schizophrenia/psychosis/schizophrenia spectrum disorder, and in 14 studies on carers of persons with bipolar disorder. However, it was not used in any identified study on carers of persons with substance use disorder.

Almost all studies did not adopt restrictive inclusion criteria regarding carers, except one study in carers of persons with schizophrenia including only mothers (Koolaee & Etemdai, 2009) and studies on carers of persons with substance use disorder limited the intervention to patients' wives (Hojjat et al, 2016), spouses (Karimi et al, 2019; Osilla et al, 2017) or children (Reupert et al, 2018).

Various validated assessment tools were used to assess family burden (e.g. the Zarit Caregiver Burden Scale, ZCBS; or the Family Assessment Device, FAD); carers' coping strategies (e.g. the Family Coping Questionnaire, FCQ; or the Coping Orientation to Problems Experienced, COPE); carers' quality of life (e.g. the WHO-QOL-BREF or the WHOQOL-100); or carers' well-being (e.g. the Carer Well-being and Support, CWS; the Experience of Caregiving Inventory, ECI); or carers' levels of knowledge (e.g. Knowledge About Schizophrenia Interview, KASI; or Illness Perception Questionnaire for Schizophrenia-Relatives, IPQS-R; or Mental Health Literacy Scale, MHLS; or Brief Illness Perception Questionnaire, Brief IPQ).

Almost all included interventions (n = 56, 84.8%) had a significant positive effect on the considered outcomes. In three studies on carers of persons with schizophrenia/psychosis/schizophrenia spectrum disorder (Szmukler et al., 1996; 2003; Posner et al., 1992) and in one study on carers of persons with bipolar disorder (Reinares et al., 2004) only a partial positive effect was found. In three studies on carers of persons with schizophrenia/psychosis/schizophrenia spectrum disorder (Shiraishi et al, 2019; Hamza et al, 2019; Day et al, 2017) and in three studies on carers of persons with bipolar disorder (de Souza et al, 2016; Abad et al, 2021; O'Donnell et al, 2020) no positive effect was found.

3.2.1. Studies on carers of persons with schizophrenia/psychosis/schizophrenia spectrum disorder (n = 47)

Forty-seven studies on carers of persons with schizophrenia/psychosis/schizophrenia spectrum disorder were identified. All details are reported in Table 1.

The studies were conducted most frequently in Hong-Kong (Chien et al, 2004, 2016, 2018, 2020; Cheng et al., 2005; So et al. 2006; Zhou et al, 2020a,b), Australia (Day et al, 2017; Deane et al, 2015; Gleeson et al, 2017; McCann et al, 2012, 2017; Szmukler et al., 1996, 2003) and United Kingdom (Leavey et al., 2004; Lobban et al., 2004, 2020; Smith & Birchwood, 1987).

The majority of the studies had an RCT design. A pre-test/post-test design was adopted only in eight studies (Ata et al, 2017; Bulut et al, 2016; Day et al, 2017; Friedman-Yakoobian et al, 2016; Gleeson et al, 2017; Kordas et al, 2015; Verma et al, 2019; Reupert et al, 2018) and a non-equivalent control group design in one study (Chou et al., 2002).

The sample mainly consisted of carers of persons with a diagnosis of schizophrenia, although four studies (Chien et al, 2016, 2018, 2020; Lobban et al, 2012) included carers of persons with recent onset of psychosis, seven recruited carers of persons with first episode psychosis (Leavey et al., 2004; So et al., 2006; McCann et al, 2012; Day et al, 2017; Gleeson et al, 2017; McCann et al, 2017; Oksuz et al, 2017), and one included carers of persons with either recent onset or chronic psychosis (Shiraishi et al, 2019). The study by Deane et al (2015) included carers of persons affected by psychosis (without further specifications). The study by Lobban et al (2020) included carers of persons with either psychosis or bipolar disorder (and is therefore included in both Tables 1 and 2).

Ad-hoc assessment tools were used only in four studies (Day et al, 2017; Kordas et al, 2015; Gutiérrez-Maldonado & Caqueo-Urizar, 2007; Ngoc et al, 2016). Among validated assessment tools, the Experience of Caregiving Inventory (ECI) was used in ten studies (Chien et al, 2016, 2020; Deane et al, 2015; Smeerdijk et al, 2015; Zhou et al, 2020a,b; So et al, 2006; Szmukler et al, 1996, 2003; McCann et al, 2012) and the Burden Assessment Schedule (BAS) in five studies (Amaresha et al, 2018; Friedman-Yakoobian et al, 2016; Hamza et al, 2019; Kumar et al, 2020; Weisman de Mamani & Suro, 2016).

A psychoeducational programme/approach was used in the majority of studies, while five studies (Chien et al, 2016, 2018; Hamza et al, 2019; McCann et al, 2017; Lobban et al., 2012) used a self-help intervention, two studies used a mutual support group approach (Chien et al., 2004; Chou et al., 2002) and one used bibliotherapy (McCann et al., Australia (2012). Almost all interventions had a positive effect on the considered outcomes (i.e. reduction of personal burden and/or improvement in quality of life). In three studies on carers of persons with schizophrenia/psychosis/schizophrenia spectrum disorder (Szmukler et al., 1996; 2003; Posner et al., 1992) only a partial positive effect was found. In three studies on carers of persons with schizophrenia/psychosis/schizophrenia spectrum disorder (Shiraishi et al, 2019; Hamza et al, 2019; Day et al, 2017) no positive effect was found.

3.2.2. Studies on carers of persons with bipolar disorder (n=15)

Fifteen studies on carers of persons with bipolar disorder were identified. All details are reported in Table 2.

The studies were conducted most frequently in Italy (Fiorillo et al, 2015; Luciano et al, 2015; Sampogna et al, 2018), Australia (Hubbard et al, 2016; Reupert et al, 2016) and the US (Perlick et al, 2018; O'Donnell et al, 2020).

The majority of the studies had an RCT design. A pre-test/post-test design was adopted only in three studies (Gex-Fabry et al, 2015; Reupert et al, 2018; Zyto et al, 2020).

Ad-hoc assessment tools were used only in the study by Hubbard et al (2016). There was a wide variability in the validated assessment tools used in the other studies (See Table 2).

One study included carers of persons with either schizophrenia or bipolar disorder (Lobban et al., 2020), and is therefore included in both Tables 1 and 2. One study included carers of persons with either bipolar disorder or substance use disorder (Reupert et al, 2018), and is therefore included in both Tables 2 and 3.

A psychoeducational programme was adopted in eleven studies, either as a single-family (Fiorillo et al, 2015; Luciano et al, 2015; Sampogna et al, 2018) or as a group approach (Gex-Fabry et al, 2015; Madigan et al, 2012). All studies except one (de Souza et al, 2016) reported a positive effect of the intervention on the considered outcomes (i.e. improvement of levels of burden, self-efficacy and/or quality of life).

3.2.3. Studies on carers of persons with substance use disorder (n=4)

Four studies on carers of persons with substance use disorder were identified. All details are reported in Table 3.

The studies were conducted most frequently in Iran (Karimi et al, 2019; Hojjat et al, 2016).

Two studies had an RCT design, whereas a pre-test/post-test design was adopted in the other two (Hojjat et al, 2016; Reupert et al, 2018). In all studies, validated assessment tools were used.

One study included carers of persons with either bipolar disorder or substance use disorder (Reupert et al, 2018), and is therefore included in both Tables 2 and 3.

An educational/informative approach was used in two studies (Hojjat et al, 2016; Karimi et al, 2019). No study used a psychoeducational approach. All interventions were effective in improving levels of quality of life and/or in reducing anxiety/depressive symptoms. No studies identifying burden as main outcome were found.

3.3. Grading the Evidence

Table 1. Psychosocial interventions compared to treatment as usual, usual psychiatric care, or waiting list for carers of persons with psychosis

Author(s): Gaia Sampogna, Mario Luciano and Andrea Fiorillo, Department of Mental Health, University of Campania “L. Vanvitelli”, Naples, Italy

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	psychosocial interventions	placebo	Relative (95% CI)	Absolute (95% CI)		
Personal Burden (assessed with: Burden Assessment Schedule or Zarit Caregiver Burden Scale or Family Burden Interview Schedule or Burden Assessment scale or Caregiver Burden Inventory or Family Burden Questionnaire)												
22	randomized trials	not serious	serious[a]	not serious	not serious	none	971	820	-	SMD **0.61 SD lower** (0.86 lower to 0.36 lower)	⊕⊕⊕◯ Moderate	CRITICAL
Well-being/quality of life (assessed with: General Health Questionnaire or Psychological Well-being or Well-being Medical Outcomes Study: Social Support Survey or WHOQOL-Brief or Carer well-being and Support Questionnaire or Quality of Life Enjoyment and Satisfaction Questionnaire or Quality of Life Interview or Quality of Life Scale or Ryff Psychological Well-being Scale or Mental Health Inventory)												
18	randomized trials	not serious	serious[a]	not serious	not serious	none	1021	920	-	SMD **0.72 SD higher** (0.39 higher to 1.05 higher)	⊕⊕⊕◯ Moderate	CRITICAL
Depressive symptoms (assessed with: Depression Anxiety Stress Scale (DASS) or Beck Depression Inventory (BDI) or Kessler Psychological Distress or Positive and Negative Affects Scale)												

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	psychosocial interventions	placebo	Relative (95% CI)	Absolute (95% CI)		
6	randomized trials	not serious	serious[a]	not serious	serious[b,c]	none	271	247	-	SMD **0.76 SD lower** (1.61 lower to 0.1 higher)	⊕⊕◯◯ Low	CRITICAL
Knowledge about the disorder (assessed with: Knowledge about schizophrenia interview or illness perception questionnaire for schizophrenia-relatives or ad-hoc questionnaire or knowledge about psychosis scale or Schizophrenia Knowledge Test (SKT))												
7	randomized trials	not serious	serious[a]	not serious	serious[c]	none	207	162	-	SMD **0.6 SD higher** (0.2 higher to 1.01 higher)	⊕⊕◯◯ Low	IMPORTANT
Skills/coping skills (assessed with: Family Coping Questionnaire or Social Problem-Solving Inventory Revised Short Form or Brief COPE or COPE)												
9	randomized trials	not serious	serious[a]	not serious	serious[b]	none	754	692	-	SMD **0.1 SD higher** (0.21 lower to 0.41 higher)	⊕⊕◯◯ Low	IMPORTANT
Self-efficacy (assessed with: General Perceived Self-Efficacy Scale (SES) or Caregiving Self- Efficacy Scale (CSS))												

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	psychosocial interventions	placebo	Relative (95% CI)	Absolute (95% CI)		
2	randomized trials	serious	serious[a]	not serious	serious[b]	none	67	67	-	SMD **1.15 SD higher** (6.16 lower to 8.46 higher)	⨁◯◯◯ Very low	IMPORTANT

CI: confidence interval; **SMD:** standardized mean difference

a. Severe, unexplained, heterogeneity ($I^2 \geq 60\%$ or $Chi^2 < 0.05$).

b. Wide CI crossing the line of no effect.

c. Less than 400 participants.

Table 2. Psychosocial interventions compared to treatment as usual, usual psychiatric care, or waiting list for carers of persons with bipolar disorder

Author(s): Gaia Sampogna, Mario Luciano and Andrea Fiorillo, Department of Mental Health, University of Campania "L. Vanvitelli", Naples, Italy

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	psychosocial interventions	placebo	Relative (95% CI)	Absolute (95% CI)		
Personal Burden (assessed with: Family Burden Self-Report Scale or Family Burden Interview Schedule or Family Problem Questionnaire or Burden Assessment Scale or Involvement Evaluation Questionnaire (IEQ))												
7	randomized trials	not serious	serious[a]	not serious	not serious	none	343	290	-	SMD **1.15 SD lower** (2 lower to 0.3 lower)	⊕⊕⊕◯ Moderate	CRITICAL
Well-being/quality of life (assessed with: Health Survey-36-Item Short Form or General Health Questionnaire-28 or Mental Health Continuum short form or Carer Well-being and Support Questionnaire or WHOQOL-BREF)												
6	randomized trials	not serious	serious[a]	not serious	serious[b]	none	518	439	-	SMD **1.08 SD higher** (0.27 lower to 2.44 higher)	⊕⊕◯◯ Low	CRITICAL
Depressive symptoms (assessed with: Depression Anxiety Stress Scale (DASS))												
3	randomized trials	not serious	serious[a]	not serious	serious[c]	none	69	68	-	SMD **3.7 SD lower** (6.95 lower to 0.45 lower)	⊕⊕◯◯ Low	CRITICAL
Knowledge about the disorder (assessed with: Mental Health Literacy Scale or ad-hoc scale on knowledge about the disorder or Brief Illness Perception Questionnaire or Knowledge of Illness Questionnaire (KOIQ) or Bipolar Disorder Knowledge Questionnaire)												

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	psychosocial interventions	placebo	Relative (95% CI)	Absolute (95% CI)		
4	randomized trials	not serious	serious[a]	not serious	serious[b,c]	none	103	74	-	SMD **0.72 SD higher** (0.42 lower to 1.86 higher)	⨁⨁◯◯ Low	IMPORTANT
Skills/coping skills (assessed with: Brief COPE or COPE or Family Problem Questionnaire)												
3	randomized trials	not serious	serious[a]	not serious	serious[b]	none	502	499	-	SMD **0.24 SD higher** (0.47 lower to 0.95 higher)	⨁⨁◯◯ Low	IMPORTANT
Self-efficacy (assessed with: Ad-hoc questionnaire or General Self-efficacy scale)												
3	randomized trials	not serious	serious[a]	not serious	serious[b,c]	none	61	73	-	SMD **1.42 SD higher** (0.29 lower to 3.14 higher)	⨁⨁◯◯ Low	IMPORTANT

CI: confidence interval; **SMD:** standardized mean difference

a. Severe, unexplained, heterogeneity (I^2 ≥60% or Chi^2 < 0.05).

b. Wide CI crossing the line of no effect.

c. Less than 400 participants.

Table 3. Psychosocial interventions compared to treatment as usual, usual psychiatric care, or waiting list for carers of persons with substance use disorders

Author(s): Gaia Sampogna, Mario Luciano and Andrea Fiorillo, Department of Mental Health, University of Campania “L. Vanvitelli”, Naples, Italy

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	psychosocial interventions	placebo	Relative (95% CI)	Absolute (95% CI)		
Burden												
None									not estimable		-	CRITICAL
Well-being/quality of life (assessed with: Mental Health Continuum short form or Carer Well-being and Satisfaction with Life Scale)												
1	randomized trial	not serious	serious[a]	not serious	serious[b,c]	none	71	40	-	SMD **0.85 SD higher** (0.4 higher to 1.31 higher)	⊕⊕◯◯ Low	CRITICAL
Depressive symptoms (assessed with: Depression Anxiety Stress Scale (DASS))												
3	randomized trials	not serious	serious[a]	not serious	serious[b,c]	none	169	207	-	SMD **0.25 SD lower** (0.85 lower to 0.35 higher)	⊕⊕◯◯ Low	CRITICAL
Knowledge about the disorder (assessed with: Mental Health Literacy Scale)												

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	**Study design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**psychosocial interventions**	**placebo**	**Relative (95% CI)**	**Absolute (95% CI)**		
1	observational studies	very serious	serious[a]	not serious	serious[b,c]	none	31	0	-	MD **0.09 higher** (8.73 lower to 8.91 higher)	⊕◯◯◯ Very low	IMPORTANT
Skills/coping skills (assessed with: COPE)												
1	observational studies	very serious	serious[a]	not serious	serious[b,c]	none	31	0	-	MD **0.04 SD higher** (0.46 lower to 0.54 higher)	⊕◯◯◯ Very low	IMPORTANT
Self-efficacy (assessed with: General Self-efficacy scale)												
1	observational studies	very serious	serious[a]	not serious	Serious[b,c]	none	31	0	-	MD **2.38 SD higher** (5.52 lower to 10.8 higher)	⊕◯◯◯ Very low[f]	IMPORTANT

CI: confidence interval; **MD:** mean difference; **SMD:** standardized mean difference

a. Severe, unexplained, heterogeneity ($I^2 \geq 60\%$ or $Chi^2 < 0.05$).

b. Wide CI crossing the line of no effect. c. Less than 400 participants.

3.4. Grading the Evidence

N/a.

3.5. Additional evidence not mentioned in GRADE tables

No additional evidence was included.

4. From Evidence to Recommendations

4.1. Summary of findings

The evidence collected in this systematic review suggests that the most frequent psychosocial intervention provided to carers is represented by psychoeducational interventions.

Other types of psychosocial interventions provided to carers of persons with psychosis, bipolar disorder or substance use disorder include self-help interventions (Chien et al, 2016; 2020; Hamza et al, 2019; McCann et al, 2017; Lobban et al, 2012); family-led mutual support group (Chien et al, 2008, 2018); peer-led mutual support group (Chien et al, 2008b); Professionally lead support group (Chou et al., 2022); family-focused culturally-informed treatment for schizophrenia (O'Donnell et al, 2020; Perlick et al, 2018); brief cognitive behavioural stress management programme (Ata & Doğan, 2017); bibliotherapy intervention (McCann et al, 2012), supportive-educational intervention (Karimi et al, 2019; Budiono et al, 2021; Hojjat et al, 2016; Deane et al, 2015; So et al, 2006), online interventions (Gleeson et al, 2017; Reupert et al, 2018; Osilla et al, 2017).
Different psychoeducational approaches are available, sharing some core features such as the provision of problem-solving techniques (Brown & Weisman de Mamani, 2018; Bulut et al, 2016; Chien et al, 2016, 2018, 2020; Friedman-Yakoobian et al, 2016; McCann et al, 2017; Abad et al, 2021; Barbeito et al, 2021; Fiorillo et al, 2015; Gex-Fabry et al, 2015; Hubbard et al, 2016; Luciano et al, 2015; O'Donnell et al, 2020; Perlick et al, 2018; Sampogna et al, 2018; Reinares et al, 2004; Sharif et al, 2012), teaching of coping strategies (Amaresha et al, 2018; Brown & Weisman de Mamani, 2018; Bulut et al, 2016; Gleeson et al, 2017; Kumar et al, 2020; Mubin et al, 2019; Zhou et al, 2020b; Hubbard et al, 2016; Reupert et al, 2018; Madigan et al, 2012; Reinares et al, 2004; Chen & Chan, 2005) and communication skills (Brown & Weisman de Mamani, 2018; Bulut et al, 2016; Gleeson et al, 2017; Kordas et al, 2015; Kumar et al, 2020; McCann et al, 2017; Ngoc et al, 2016; Öksüz et al, 2017; Puspitosari et al, 2019; Rami et al, 2018; Sharma et al, 2021; Shiraishi et al, 2019; Zhou et al, 2020b; Fiorillo et al, 2015; Hubbard et al, 2016; Luciano et al, 2015; O'Donnell et al, 2020; Sampogna et al, 2018; Reinares et al, 2004; Gutiérrez-Maldonado & Caqueo-Urizar, 2007; Koolaee & Etemdai, 2009; Leavey et al, 2004).

Psychosocial interventions (including psychoeducation, self-help interventions, family-led and professionally led mutual support group, and family-focused culturally informed treatment) are effective in reducing the levels of subjective and objective burden in carers of persons with schizophrenia/psychosis/schizophrenia spectrum disorder and with bipolar disorder with a moderate level of certainty. The four available studies focusing on carers of persons with substance use disorder, do not provide data about the effectiveness of psychosocial interventions used in this population on this outcome.

Psychoeducation, brief cognitive behavioural stress management programme, information booklet with interactive newsletters, collective narrative therapy, online intervention ("mi.spot"), moderate online social therapy (MOST) have a significant effect towards improving quality of life/well-being in carers of persons with schizophrenia/psychosis/schizophrenia spectrum disorder and bipolar disorder with a moderate certainty of evidence. In carers of persons with substance use disorders supportive-educational intervention, and online intervention ("mi.spot") were associated with an improvement in quality of life/well-being, but with a low level of certainty of evidence.

Family psychoeducation, professionally lead support group and online intervention ("mi.spot") have a positive effect on depressive symptoms in carers of persons with schizophrenia/psychosis/schizophrenia spectrum disorder and bipolar disorder, with a low level of certainty of evidence.

Supportive-educational intervention and online intervention (“mi.spot”) have a positive effect on the levels of depressive symptoms in carers of persons with substance use disorders, but with a low level of certainty of evidence.

Psychoeducation (including brief programme, family intervention or multifamily group approach) and educational video materials have a positive effect towards improving levels of knowledge about the disorder in carers of persons with schizophrenia/psychosis/schizophrenia spectrum disorder and bipolar disorder, with a low level of certainty of evidence.

Online interventions providing information on the disorder and teaching coping strategies have a positive impact on the levels of knowledge of carers of persons with substance use disorders, with a very low level of certainty of evidence.

Brief cognitive behavioural stress management programme, self-help problem-solving-based manual guided self-learning programme, psychoeducational programme, educational video materials, self-help problem-solving bibliotherapy, and online intervention have a positive impact on skills/coping skills in carers of persons with schizophrenia/psychosis/schizophrenia spectrum disorder and bipolar disorder. The levels of certainty are low and moderate, respectively.

In carers of persons with substance use disorders, only the online intervention (“mi.spot”), providing information on the disorder and teaching coping strategies, produced an improvement in coping skills, but with a very low level of certainty.

Professionally-lead support group and psychoeducational programme have a positive effect in carers of persons with schizophrenia/psychosis/schizophrenia spectrum disorder, with a very low level of certainty of evidence. Online intervention (mi.spot) and brief psychoeducational intervention have a positive effect in carers of persons with bipolar disorder, with a very low level of certainty of evidence. In carers of persons with substance use disorders, only the online intervention (“mi.spot”) produced an improvement in self-efficacy levels, but with a very low level of certainty.

Table 4. GRADE table 1

GRADE Table	Outcome	Specific Outcome	Number of Studies	Effects	Certainty of Evidence
Grade Table 1: Psychosocial interventions compared to treatment as usual, usual psychiatric care, or waiting list for carers of persons with psychosis	Personal burden	-	22	**SMD 0.61 SD lower*** (0.86 lower to 0.36 lower)	⊕⊕⊕◯ Moderate
	Well-being/quality of life	-	18	**SMD 0.72 SD higher*** (0.39 higher to 1.05 higher)	⊕⊕⊕◯ Moderate
	Depressive symptoms	-	6	**SMD 0.76 SD lower** (1.61 lower to 0.1 higher)	⊕⊕◯◯ Low
	Knowledge about the disorder	-	7	**SMD 0.6 SD higher*** (0.2 higher to 1.01 higher)	⊕⊕◯◯ Low
	Skills/coping skills	-	8	**SMD 0.1 SD higher** (0.21 lower to 0.41 higher)	⊕⊕◯◯ Low
	Self-efficacy	-	2	**SMD 1.15 SD higher*** (6.16 lower to 8.46 higher)	⊕◯◯◯ Very Low

SMD: standardized mean difference
*Statistically significant

Table 5. GRADE table 2

GRADE Table	Outcome	Specific Outcome	Number of Studies	Effects	Certainty of Evidence
Grade Table 2: Psychosocial interventions compared to treatment as usual, usual psychiatric care, or waiting list for carers of persons with bipolar disorder	Personal burden	-	7	**SMD 1.15 SD lower*** (2 lower to 0.3 lower)	⊕⊕⊕◯ Moderate
	Well-being/quality of life	-	6	**SMD 1.08 SD higher** (0.27 lower to 2.44 higher)	⊕⊕◯◯ Low
	Depressive symptoms	-	3	**SMD 3.7 SD lower*** (6.95 lower to 0.45 lower)	⊕⊕◯◯ Low
	Knowledge about the disorder	-	4	**SMD 0.72 SD higher** (0.42 lower to 1.86 higher)	⊕⊕◯◯ Low
	Skills/coping skills	-	3	**SMD 0.24 SD higher** (0.47 lower to 0.95 higher)	⊕⊕◯◯ Low
	Self-efficacy	-	3	**SMD 1.42 SD higher** (0.29 lower to 3.14 higher)	⊕⊕◯◯ Low

SMD: standardized mean difference
*Statistically significant

Table 6. GRADE table 3

GRADE Table	Outcome	Specific Outcome	Number of Studies	Effects	Certainty of Evidence
Grade Table 3: Psychosocial interventions compared to treatment as usual, usual psychiatric care, or waiting list for carers of persons with substance use disorders	Personal burden	-	-	-	N/A
	Well-being/quality of life	-	2	**SMD 0.85 SD higher*** (0.4 higher to 1.31 higher)	⊕⊕◯◯ Low
	Depressive symptoms	-	2	**SMD 0.25 SD lower** (0.85 lower to 0.35 higher)	⊕⊕◯◯ Low
	Knowledge about the disorder	-	1	**MD 0.09 SD higher** (8.73 lower to 8.91 higher)	⊕◯◯◯ Very low
	Skills/coping skills	-	1	**MD 0.04 SD higher** (0.46 lower to 0.54 higher)	⊕◯◯◯ Very low
	Self-efficacy	-	1	**MD 2.38 SD higher** (5.52 lower to 10.8 higher)	⊕◯◯◯ Very low

SMD: standardized mean difference, MD: mean difference
*Statistically significant

Table 7. GRADE table 4

GRADE Table	Outcome	Subgroup analysis	Number of Studies	Effects	Certainty of Evidence
Grade Table 4: Psychosocial interventions compared to treatment as usual, usual psychiatric care, or waiting list for carers of persons with psychosis	Personal burden	-	22	**SMD 0.61 lower*** (0.86 lower to 0.36 lower)	⊕⊕⊕◯ Moderate
		Psychoeducation	13	SMD 0.70 lower* (1.01 lower to 0.40 lower)	⊕⊕⊕◯ Moderate
		Supportive-Educational interventions	2	SMD 0.26 lower* (0.67 lower to 0.14 higher)	⊕⊕◯◯ Low
		Stress management	1	MD 0.73 lower* (1.25 lower to 0.21 lower)	⊕◯◯◯ Very low
		Collective Narrative Therapy	1	-	
		Family-Led Mutual Support	3	SMD 0.72 lower (1.73 lower to 0.29 higher)	⊕⊕◯◯ Low
		Yoga intervention	1	MD 0.29 (0.28 lower to 0.36 lower)	⊕◯◯◯ Very low
	Well-being/Quality of life	-	18	**SMD 0.72 higher*** (0.39 higher to 1.05 higher)	⊕⊕⊕◯ Moderate
		Psychoeducation	10	SMD 1.04 higher (0.53 higher to 1.54 higher)	⊕⊕⊕◯ Moderate
		Supportive-Educational interventions	2	SMD 0.13 higher (0.70 lower to 0.97 higher)	⊕⊕◯◯ Low
		Stress management	1	MD 0.41 higher (0.10 lower to 0.92 higher)	⊕◯◯◯ Very low
		Collective Narrative Therapy	1	MD 0.38 higher (0.12 lower to 0.87 higher)	⊕◯◯◯ Very low
		Family-Led Mutual Support	3	SMD 0.88 higher (0.46 higher to 1.29 higher)	⊕⊕◯◯ Low

GRADE Table	Outcome	Subgroup analysis	Number of Studies	Effects	Certainty of Evidence
		Yoga intervention	1	MD 0.27 higher (0.30 lower to 0.84 higher)	⊕◯◯◯ Very low
	Depressive symptoms	-	6	**SMD 0.76 lower** (1.61 lower to 0.1 higher)	⊕⊕◯◯ Low
		Psychoeducation	1	MD 1.57 lower (1.98 lower to 1.17 lower)	⊕◯◯◯ Very low
		Supportive-Educational interventions	1	MD 0.33 lower (0.66 lower to 0.00 lower)	⊕◯◯◯ Very low
		Stress management		-	
		Collective Narrative Therapy		-	
		Family-Led Mutual Support		-	
		Yoga intervention		-	
	Knowledge about the disorder	-	7	**SMD 0.6 higher*** (0.2 higher to 1.01 higher)	⊕⊕◯◯ Low
		Psychoeducation	4	SMD 0.65 higher* (0.30 higher to 0.99 higher)	⊕⊕◯◯ Low
		Supportive-Educational interventions	3	SMD 0.61 (0.40 lower to 1.62 higher)	⊕⊕◯◯ Low
		Stress management		**-**	
		Collective Narrative Therapy		**-**	
		Family-Led Mutual Support		**-**	
		Yoga intervention		**-**	

GRADE Table	Outcome	Subgroup analysis	Number of Studies	Effects	Certainty of Evidence
	Skills/coping skills	-	8	**SMD 0.10 higher** (0.21 lower to 0.41 higher)	⊕⊕◯◯ Low
		Psychoeducation	6	SMD 0.17 higher (0.19 lower to 0.52 higher)	⊕⊕◯◯ Low
		Supportive-Educational interventions	2	SMD 0.45 lower (0.94 lower to 0.05 higher)	⊕⊕◯◯ Low
		Stress management	1	MD 0.73 higher* (0.21 higher to 1.25 higher)	⊕◯◯◯ Very low
		Collective Narrative Therapy		-	
		Family-Led Mutual Support		-	
		Yoga intervention		-	
	Self-efficacy	-	2	**SMD 1.15 higher** (6.16 lower to 8.46 higher)	⊕◯◯◯ Very Low
		Psychoeducation	2	SMD 1.15 higher (6.16 lower to 8.46 higher)	⊕◯◯◯ Very Low
		Supportive-Educational interventions		-	
		Stress management		-	
		Collective Narrative Therapy		-	
		Family-Led Mutual Support		-	
		Yoga intervention		-	

*Statistically significant

Table 8. GRADE table 5

GRADE Table	Outcome	Subgroup analysis	Number of Studies	Effects	Certainty of Evidence
Grade Table 5: Psychosocial interventions compared to treatment as usual, usual psychiatric care, or waiting list for carers of persons with bipolar disorder	Personal burden	-	7	**SMD 1.15 lower*** (2 lower to 0.3 lower)	⊕⊕⊕◯ Moderate
	Psychoeducation	Psychoeducation	6	SMD 0.63 lower* (1.31 lower to 0.06 lower)	⊕⊕⊕◯ Moderate
		Supportive-Educational interventions	-	-	
		Stress management	--	-	
		Collective Narrative Therapy	-	-	
		Family-Led Mutual Support	1	MD 4.03 lower* (5.11 lower to 2.95 lower)	⊕◯◯◯ Very low
		Yoga intervention	-	-	
		Family focused intervention	-	-	
		Online intervention (“mi.spot”)	-	-	
	Well-being/quality of life	-	6	**SMD 1.08 higher** (0.27 lower to 2.44 higher)	⊕⊕◯◯ Low
		Psychoeducation	5	SMD 0.27 higher (0.22 lower to 0.76 higher)	⊕⊕◯◯ Low
		Supportive-Educational interventions		-	
		Stress management		-	

GRADE Table	Outcome	Subgroup analysis	Number of Studies	Effects	Certainty of Evidence
		Collective Narrative Therapy		-	
		Family-Led Mutual Support		-	
		Yoga intervention		-	
		Family focused intervention	1	MD 2.62 higher* (1.78 higher to 3.46 higher)	⊕◯◯◯ Very low
		Online intervention (“mi.spot”)		-	
	Depressive symptoms	-	3	**SMD 3.70 lower*** (6.95 lower to 0.45 lower)	⊕⊕◯◯ Low
		Psychoeducation	1	MD 1.47 lower* (3.18 lower to 0.24 lower)	⊕◯◯◯ Very Low
		Supportive-Educational interventions		-	
		Stress management		-	
		Collective Narrative Therapy		-	
		Family-Led Mutual Support		-	
		Yoga intervention		-	
		Family focused intervention	1	MD 5.46 lower* (6.85 lower to 4.07 lower)	⊕◯◯◯ Very Low
		Online intervention (“mi.spot”)	1	MD 4.58 lower* (10.40 lower to 1.24 lower)	⊕◯◯◯ Very Low
	Knowledge about the disorder	-	4	**SMD 0.72 higher** (0.42 lower to 1.86 higher)	⊕⊕◯◯ Low

GRADE Table	Outcome	Subgroup analysis	Number of Studies	Effects	Certainty of Evidence
		Psychoeducation	2	SMD 0.98 higher (0.63 lower to 2.58 higher)	⊕⊕◯◯ Low
		Supportive-Educational interventions		-	
		Stress management		-	
		Collective Narrative Therapy		-	
		Family-Led Mutual Support		-	
		Yoga intervention		-	
		Family focused intervention		-	
		Online intervention (“mi.spot”)	1	MD 0.01 higher (0.49 lower to 0.50 higher)	⊕◯◯◯ Very Low
	Skills/coping skills	-	3	**SMD 0.24 higher** (0.47 lower to 0.95 higher)	⊕⊕◯◯ Low
		Psychoeducation	2	SMD 0.34 higher (0.71 lower to 1.38 higher)	⊕⊕◯◯ Low
		Supportive-Educational interventions		-	
		Stress management		-	
		Collective Narrative Therapy		-	
		Family-Led Mutual Support		-	

GRADE Table	Outcome	Subgroup analysis	Number of Studies	Effects	Certainty of Evidence
		Yoga intervention		-	
		Family focused intervention		-	
		Online intervention (“mi.spot”)	1	MD 0.04 higher (0.46 lower to 0.54 higher)	⊕◯◯◯ Very Low
	Self-efficacy	-	3	**SMD 1.42 higher** (0.29 lower to 3.14 higher)	⊕⊕◯◯ Low
		Psychoeducation	2	SMD 2.22 higher (1.62 lower to 6.05 higher)	⊕⊕◯◯ Low
		Supportive-Educational interventions		-	
		Stress management		-	
		Collective Narrative Therapy		-	
		Family-Led Mutual Support		-	
		Yoga intervention		-	
		Family focused intervention		-	
		Online intervention (“mi.spot”)	1	MD 0.25 higher (0.35 lower to 0.65 higher)	⊕◯◯◯ Very Low

*Statistically significant

Table 9. GRADE table 6

GRADE Table	Outcome	Subgroup analysis	Number of Studies	Effects	Certainty of Evidence
Grade Table 6: Psychosocial interventions compared to treatment as usual, usual psychiatric care, or waiting list for carers of persons with substance use disorders	Personal burden	-		-	
		Psychoeducation		-	
		Supportive-Educational interventions		-	
		Stress management		-	
		Mutual support		-	
		Yoga intervention		-	
		Family focused intervention		-	
		Online intervention		-	
	Well-being/quality of life	-	2	**SMD 0.85 higher*** (0.4 higher to 1.31 higher)	⊕⊕◯◯ Low
		Psychoeducation		-	
		Supportive-Educational interventions	1	MD 0.85 higher (0.40 higher to 1.31 higher)	⊕◯◯◯ Very Low
		Stress management		-	
		Collective Narrative Therapy		-	
		Family-Led Mutual Support		-	

GRADE Table	Outcome	Subgroup analysis	Number of Studies	Effects	Certainty of Evidence
		Yoga intervention		-	
		Family focused intervention		-	
		Online intervention	1	MD 0.01 higher (0.50 lower to 0.50 higher)	
	Depressive symptoms	-	3	**SMD 0.25 lower** (0.85 lower to 0.35 higher)	⊕◯◯◯ Very Low
		Psychoeducation		-	
		Supportive-Educational interventions	2	MD 0.67 lower (1.13 lower to 0.22 lower)	⊕◯◯◯ Very low
		Stress management		-	
		Collective Narrative Therapy		-	
		Yoga intervention		-	
		Family-Led Mutual Support		-	
		Online intervention (“mi.spot”)	1	MD 0.04 lower (0.64 lower to 0.56 lower)	⊕◯◯◯ Very low
	Knowledge about the disorder	-	1	**MD 0.09 higher** (8.73 lower to 8.91 higher)	⊕◯◯◯ Very low
		Psychoeducation		-	
		Supportive-Educational interventions		-	
		Stress management		-	

GRADE Table	Outcome	Subgroup analysis	Number of Studies	Effects	Certainty of Evidence
		Collective Narrative Therapy		-	
		Yoga intervention		-	
		Family-Led Mutual Support		-	
		Online intervention (“mi.spot”)	1	MD 0.09 higher (8.73 lower to 8.91 higher)	⊕◯◯◯ Very low
	Skills/coping skills	-	1	**MD 0.04 higher** (0.46 lower to 0.54 higher)	⊕◯◯◯ Very low
		Psychoeducation			
		Informative/educational information		-	
		Stress management		-	
		Collective Narrative Therapy		-	
		Mutual support		-	
		Yoga intervention		-	
		Family focused intervention		-	
		Online intervention (“mi.spot”)	1	MD 0.04 higher (0.46 lower to 0.54 higher)	⊕◯◯◯ Very low
	Self-efficacy	-	1	**MD 2.38 higher** (5.52 lower to 10.8 higher)	⊕◯◯◯ Very low
		Psychoeducation		-	

GRADE Table	Outcome	Subgroup analysis	Number of Studies	Effects	Certainty of Evidence
		Informative/educational information		-	
		Stress management		-	
		Collective Narrative Therapy		-	
		Mutual support		-	
		Yoga intervention		-	
		Family-Led Mutual Support		-	
		Online intervention ("mi.spot")	1	MD 2.38 higher (5.52 lower to 10.8 higher)	⊕◯◯◯ Very low

*Statistically significant

4.2. Evidence to decision

Table 10. Evidence to decision table

Please note * indicates evidence from overarching qualitative review by Gronholm et al, 2023

CRITERIA, QUESTIONS		JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
Priority of the problem	Is the problem a priority? The more serious a problem is, the more likely it is that an option that addresses the problem should be a priority (e.g. diseases that are fatal or disabling are likely to be a higher priority than diseases that only cause minor distress). The more people who are affected, the more likely it is that an option that addresses the problem should be a priority.			
	• Are the consequences of the problem serious (that is, severe or important in terms of the potential benefits or savings)? • Is the problem urgent? • Is it a recognized priority (such as based on a political or policy decision)? [Not relevant when an individual patient perspective is taken]	☐ No ☐ Probably no ☐ Probably yes ☒ **Yes** ☐ Varies ☐ Don't know	Carers of people with severe mental disorders (including schizophrenia/psychosis/schizophrenia spectrum disorder, bipolar disorder or substance use disorder) often report high levels of subjective (perceived) and objective burden, as well as other negative consequences of caring, including poor satisfaction with services provided, and difficulties in coping. Furthermore, it has been repeatedly confirmed that the burden of care and the ability of a carer to cope with relative's disorder can have an impact on the recovery of the patient. Therefore, carers of people suffering from severe mental disorders would benefit from psychosocial interventions focused on their quality of life, well-being and personal burden as an additional component of health care service provision.	

<table>
<tr><th colspan="2">CRITERIA, QUESTIONS</th><th>JUDGEMENT</th><th>RESEARCH EVIDENCE</th><th>ADDITIONAL CONSIDERATIONS</th></tr>
<tr><td rowspan="2">Desirable Effects</td><td colspan="4">How substantial are the desirable anticipated effects?
The larger the benefit, the more likely it is that an option should be recommended.</td></tr>
<tr><td>• Judgements for each outcome for which there is a desirable effect
• How substantial (large) are the desirable anticipated effects (including health and other benefits) of the option (taking into account the severity or importance of the desirable consequences and the number of people affected)?</td><td>☐ Trivial
☐ Small
☒ Moderate
☐ Large
☐ Varies
☒ Don't know</td><td>A moderate rating is proposed for the evidence on carers of persons with psychosis or bipolar disorder and a don’t know rating is proposed for the evidence on carers of persons with substance use disorders.
Personal burden
The following interventions have a significant effect collectively in reducing the levels of personal burden in carers of persons with schizophrenia/psychosis/ schizophrenia spectrum disorder and bipolar disorder: psychoeducation, self-help interventions, family-led mutual support group, and family-focused culturally-informed treatment for schizophrenia, yoga/self-help No interventions were identified focusing on reduction of personal burden in carers of people with substance use disorders.
Well-being/quality of life
The following interventions have a significant effect collectively towards improving quality of life/well-being in carers of persons with schizophrenia/psychosis/ schizophrenia spectrum disorder and bipolar disorder: psychoeducation, brief cognitive behavioural stress management programme, information booklet with interactive newsletters, collective narrative</td><td></td></tr>
</table>

CRITERIA, QUESTIONS		JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
			therapy, online intervention (“mi.spot”) providing information on the disorder and teaching coping strategies, moderate online social therapy (MOST). Self-help yoga manual intervention was associated with no effect in carers of persons with schizophrenia. The following interventions are effective **collectively** in improving quality of life/well-being in carers of persons with substance use disorders: supportive-educational intervention, and online intervention (“mi.spot”) providing information on the disorder and teaching coping strategies. **Depressive symptoms** The following interventions are effective **collectively** in improving depressive symptoms in carers of persons with schizophrenia/psychosis/ schizophrenia spectrum disorder and bipolar disorder: family psychoeducation, and online intervention (“mi.spot”) providing information on the disorder and teaching coping strategies. The following interventions are effective **collectively** in improving depressive symptoms in carers of persons with substance use disorders: supportive-educational intervention, online intervention (“mi.spot”) providing information on the disorder and teaching coping strategies.	

CRITERIA, QUESTIONS		JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
			Knowledge about the disorder The following interventions are effective **collectively** in improving levels of knowledge about the disorder in carers of persons with schizophrenia/psychosis/ schizophrenia spectrum disorder and bipolar disorder: brief psychoeducational programme, educational video materials. The following intervention is effective in improving the levels of knowledge of carers of persons with substance use disorders: online intervention ("mi.spot") providing information on the disorder and teaching coping strategies. **Skills/coping skills** The following interventions are effective **collectively** in improving coping strategies in carers of persons with schizophrenia/psychosis/schizophrenia spectrum disorder and bipolar disorder: brief cognitive behavioural stress management programme, self-help problem-solving-based manual guided self-learning programme, psychoeducational programme, educational video materials, self-help problem-solving bibliotherapy, and online intervention ("mi.spot") providing information on the disorder and teaching coping strategies. In carers of persons with substance use disorders, only the online intervention ("mi.spot") providing information on the disorder and teaching coping strategies	

CRITERIA, QUESTIONS		JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
			was found to have a moderate effect. **Self-efficacy** The following interventions **collectively** produce an improvement in levels of self-efficacy in carers of persons with schizophrenia/ psychosis/schizophrenia spectrum disorder: professionally-lead support group and psychoeducational programme. The following interventions **collectively** produce an improvement in levels of self-efficacy in carers of persons with bipolar disorder: online intervention (mi.spot) and a brief psychoeducational intervention. Only the online intervention ("mi.spot") produces an improvement in self-efficacy levels in carers of persons with substance use disorders.	
Undesirable Effects	How substantial are the undesirable anticipated effects? The greater the harm, the less likely it is that an option should be recommended.			
	• Judgements for each outcome for which there is an undesirable effect • How substantial (large) are the undesirable anticipated effects (including harms to health and other harms) of the option (taking into account the severity or importance of the adverse effects and the number of people affected)?	☐ Large ☐ Moderate ☐ Small ☐ Trivial ☐ Varies ☒ **Don't know**	None of the studies reported adverse outcomes or any harms identified as a result of any of the interventions.	

	CRITERIA, QUESTIONS	JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
Certainty of evidence	What is the overall certainty of the evidence of effects? The less certain the evidence is for critical outcomes (those that are driving a recommendation), the less likely that an option should be recommended (or the more important it is likely to be to conduct a pilot study or impact evaluation, if it is recommended).			
	• What is the overall certainty of this evidence of effects, across all of the outcomes that are critical to making a decision? • See GRADE guidance regarding detailed judgements about the quality of evidence or certainty in estimates of effects	☒ **Very low** ☐ Low ☒ **Moderate** ☐ High ☐ No included studies	**A moderate rating is proposed for the evidence on carers of persons with psychosis or bipolar disorder and a very low rating is proposed for the evidence on carers of persons with substance use disorders.** **Psychoeducation** The evidence for the use of psychoeducation to support carers of persons with schizophrenia/psychosis/ schizophrenia spectrum disorder and bipolar disorder is of moderate certainty. No evidence is available for carers of persons with substance use disorders. **Self-help interventions** The evidence for the use of self-help intervention to support carers of persons with schizophrenia/psychosis/ schizophrenia spectrum disorder is of moderate certainty. No data are available on using these interventions in carers of persons with bipolar disorder or substance use disorder. **Family-led mutual support group/family-focused culturally-informed treatment for schizophrenia** The evidence for the use family-led mutual support group/family-focused culturally-informed treatment for schizophrenia with carers of persons with	

	CRITERIA, QUESTIONS	JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
			schizophrenia/psychosis/schizophrenia spectrum disorder and bipolar disorder is of moderate certainty. No data are available on using these interventions with carers of persons with substance use disorder. **Brief cognitive behavioural stress management programme** The evidence for the use of brief cognitive behavioural stress management programme to support carers of persons with schizophrenia/psychosis/ schizophrenia spectrum disorder is of moderate certainty. No data are available on this intervention for carers of persons with bipolar disorder or substance use disorder. **Supportive-educational intervention and online intervention** The evidence for the use of educational intervention (in person and/or online) to support carers of persons with schizophrenia/psychosis/schizophrenia spectrum disorder, bipolar disorder and substance use disorder is of moderate certainty. Only one study has evaluated the efficacy of an online intervention, and it was not possible to separate the effect of the intervention according to the different diagnostic groups. Therefore, further studies are needed in order to evaluate the efficacy of online interventions for	

CRITERIA, QUESTIONS		JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
			supporting carers of persons with psychosis, bipolar disorder and substance use disorders.	
Values	Is there important uncertainty about or variability in how much people value the main outcomes? The more likely it is that differences in values would lead to different decisions, the less likely it is that there will be a consensus that an option is a priority (or the more important it is likely to be to obtain evidence of the values of those affected by the option). Values in this context refer to the relative importance of the outcomes of interest (how much people value each of those outcomes). These values are sometimes called “utility values”.			
	• Is there important uncertainty about how much people value each of the main outcomes? • Is there important variability in how much people value each of the main outcomes?	☐ Important uncertainty or variability ☐ Possibly important uncertainty or variability ☒ **Probably no important uncertainty or variability** ☐ No important uncertainty or variability	The Gronholm et al 2023 qualitative review did not directly cover the views of carers. The review was conducted to assess values, resources, cost effectiveness, health equity quality and non-discrimination, feasibility and human rights related factors in mental health care and mental health services. Overall, the studies reviewed highlighted importance and recognition of importance of mental health interventions and the outcomes of those interventions on people’s mental health and well-being. The utility value could be limited by certain factors and barriers present in the health systems. For instance, low awareness, poor funding and poor political buy-in, or other social barriers. Social networks or raising awareness can facilitate adoption and recognition of mental health issues and the perceived value of the interventions.	

CRITERIA, QUESTIONS		JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
Balance of effects	Does the balance between desirable and undesirable effects favour the intervention or the comparison? The larger the desirable effects in relation to the undesirable effects, taking into account the values of those affected (i.e. the relative value they attach to the desirable and undesirable outcomes) the more likely it is that an option should be recommended.			
	• Judgements regarding each of the four preceding criteria • To what extent do the following considerations influence the balance between the desirable and undesirable effects: - How much less people value outcomes that are in the future compared to outcomes that occur now (their discount rates)? - People's attitudes towards undesirable effects (how risk averse they are)? - People's attitudes towards desirable effects (how risk seeking they are)?	☐ Favours the comparison ☐ Probably favours the comparison **☒ Does not favour either the intervention or the comparison** **☒ Probably favours the intervention** ☐ Favours the intervention ☐ Varies ☐ Don't know	**A probably favours the intervention rating is proposed for the evidence on carers of persons with psychosis or bipolar disorder and a does not favour either the intervention or the comparison rating is proposed for the evidence on carers of persons with substance use disorders.**	
Resources required	How large are the resource requirements (costs)? The greater the cost, the less likely it is that an option should be a priority. Conversely, the greater the savings, the more likely it is that an option should be a priority.			
	• How large is the difference in each item of resource use for which fewer resources are required? • How large is the difference in each item of resource use for which more resources are required? • How large an investment of resources would the option require or save?	☐ Large costs ☐ Moderate costs ☐ Negligible costs and savings ☐ Moderate savings ☐ Large savings ☐ Varies **☒ Don't know**	No identified evidence.	

	CRITERIA, QUESTIONS	JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
Certainty of evidence of required resources	What is the certainty of the evidence of resource requirements (costs)?			
	• Have all-important items of resource use that may differ between the options being considered been identified? • How certain is the evidence of differences in resource use between the options being considered (see GRADE guidance regarding detailed judgements about the quality of evidence or certainty in estimates)? • How certain is the cost of the items of resource use that differ between the options being considered? • Is there important variability in the cost of the items of resource use that differ between the options being considered?	☐ Very low ☐ Low ☐ Moderate ☐ High ☒ **No included studies**	No identified evidence.	
Cost effectiveness	Does the cost-effectiveness of the intervention favour the intervention or the comparison? The greater the cost per unit of benefit, the less likely it is that an option should be a priority.			
	• Judgements regarding each of the six preceding criteria • Is the cost effectiveness ratio sensitive to one-way sensitivity analyses? • Is the cost effectiveness ratio sensitive to multivariable sensitivity analysis? • Is the economic evaluation on which the cost effectiveness estimate is based reliable? • Is the economic evaluation on which the cost effectiveness estimate is based applicable to the setting(s) of interest?	☐ Favours the comparison ☐ Probably favours the comparison ☐ Does not favour either the intervention or the comparison ☐ Probably favours the intervention ☐ Favours the intervention ☐ Varies ☒ **No included studies**	No identified evidence.	

CRITERIA, QUESTIONS		JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
Health equity, equality and non-discrimination	What would be the impact on health equity, equality and non-discrimination? (WHO INTEGRATE) Health equity and equality reflect a concerted and sustained effort to improve health for individuals across all populations, and to reduce avoidable systematic differences in how health and its determinants are distributed. Equality is linked to the legal principle of non-discrimination, which is designed to ensure that individuals or population groups do not experience discrimination on the basis of their sex, age, ethnicity, culture or language, sexual orientation or gender identity, disability status, education, socioeconomic status, place of residence or any other characteristics. All recommendations should be in accordance with universal human rights standards and principles. The greater the likelihood that the intervention increases health equity and/or equality and that it reduces discrimination against any particular group, the greater the likelihood of a general recommendation in favour of this intervention.			
	• How are the condition and its determinants distributed across different population groups? Is the intervention likely to reduce or increase existing health inequalities and/or health inequities? Does the intervention prioritize and/or aid those furthest behind? • How are the benefits and harms of the intervention distributed across the population? Who carries the burden (e.g. all), who benefits (e.g. a very small sub-group)? • How affordable is the intervention for individuals, workplaces or communities? • How accessible - in terms of physical as well as informational access - is the intervention across different population groups? • Is there any suitable alternative to addressing the condition, does the intervention represent the only available option? Is this option proportionate to the need, and will it be subject to periodic review?	☐ Reduced ☐ Probably reduced ☐ Probably no impact ☒ **Probably increased** ☐ Increased ☐ Varies ☐ Don't know	Though not directly related to carers, Gronholm et al 2023 qualitative review mentioned that homelessness, poverty, lack of education and stigma contributed to people not seeking treatment. The factors identified here: • **Education**: Basic issues like knowledge of where to seek treatment and low literacy challenged access to care • **Finances**: People who need treatment also might consider that support-seeking process may lead to lost wages and possible disapproval from the employers. • **Stigma**: Treatment seeking, especially in designated facilities, makes patients easily identifiable and results in them facing discrimination by other members of the society or being tracked by law enforcement. Stigma was of a greater concern among women and acted as a significant barrier of support seeking. • Carers can experience ‘courtesy’ discrimination and stigma which presents a barriers to seeking	

CRITERIA, QUESTIONS		JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
			support e.g. Corrigan et al, 2004	
Feasibility	Is the intervention feasible to implement? The less feasible (capable of being accomplished or brought about) an option is, the less likely it is that it should be recommended (i.e. the more barriers there are that would be difficult to overcome).			
	• Can the option be accomplished or brought about? • Is the intervention or option sustainable? • Are there important barriers that are likely to limit the feasibility of implementing the intervention (option) or require consideration when implementing it?	☐ No ☐ Probably no ☐ Probably yes ☐ Yes ☒ **Varies** ☐ Don't know	Gronholm et al 2023 qualitative review Barriers included fragmented health services and people not thinking that they have any health problems. These barriers in addition to the once listed above can have an effect on how and if people seek the treatment and if they continue to visit the health care facilities for treatment. In addition: feasibility considerations include: • Acceptability of interventions for stakeholders • Health worker workload, competency - requires training, refreshers, supervision; networking with others in same role. • Availability of a task-sharing workforce; • Participant education and literacy requires verbal explanations/tasks; • Logistical issues - such as e.g. mobile populations, affordability of travel to receive care, lack of private space; • Limited resources/mental health budget.	

CRITERIA, QUESTIONS		JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
Human rights and sociocultural acceptability	Is the intervention aligned with human rights principles and socioculturally acceptable? (WHO INTEGRATE) This criterion encompasses two distinct constructs: The first refers to an intervention's compliance with universal human rights standards and other considerations laid out in international human rights law beyond the right to health (as the right to health provides the basis of other criteria and sub-criteria in this framework). The second, sociocultural acceptability, is highly time-specific and context-specific and reflects the extent to which those implementing or benefiting from an intervention as well as other relevant stakeholder groups consider it to be appropriate, based on anticipated or experienced cognitive and emotional responses to the intervention. The greater the sociocultural acceptability of an intervention to all or most relevant stakeholders, the greater the likelihood of a general recommendation in favour of this intervention.			
	• Is the intervention in accordance with universal human rights standards and principles? • Is the intervention socioculturally acceptable to patients/beneficiaries as well as to those implementing it? To which extent do patients/beneficiaries value different non-health outcomes? • Is the intervention socioculturally acceptable to the public and other relevant stakeholder groups? Is the intervention sensitive to sex, age, ethnicity, culture or language, sexual orientation or gender identity, disability status, education, socioeconomic status, place of residence or any other relevant characteristics? • How does the intervention affect an individual's, population group's or organization's autonomy, i.e. their ability to make a competent, informed and voluntary decision? • How intrusive is the intervention, ranging from low intrusiveness (e.g. providing information) to intermediate intrusiveness (e.g. guiding choices) to high intrusiveness (e.g. restricting or eliminating choices)? Where applicable, are high intrusiveness and/or impacts on the privacy and dignity of concerned stakeholders justified?	☐ No ☐ Probably no ☐ Probably yes ☐ Yes ☒ **Varies** ☐ Don't know	Gronholm et al 2023 qualitative review *A number of considerations were noted which would impact the right to health and access to health care. For example **stigma and discrimination** were identified as barriers that affect the help-seeking. **Lack of confidentiality** is another factor that can deter people from accessing care or receiving confidential and safe mental health care. A range of stigma-related concerns were flagged up: • Social stigma and exclusion due to substance use • Fear of being seen in designated health facilities • Facing discrimination by other members of society • Concerns around being tracked by law enforcement Mitigating steps proposed by the review: • Awareness activities to reduce the stigma towards those with severe mental disorders and their carers • Training health personnel to obtain additional skills and empower them	

CRITERIA, QUESTIONS		JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
			to provide care - Care for a patients with severe mental disorders to also include provision of empathetic support and supportive communication. Training on communication and professional factors of service delivery (like confidentiality, positive outlook of future, linkages of care) would probably reduce the stigma and make a health care system more palatable. **Financial issues** around the treatment can also be a barrier that limits access to those who need to seek help. Mitigating steps proposed by the review: - low-cost scalable solutions to make treatment available to different parts of the country would be helpful to make care accessible to a more people. Using telemedicine and telehealth as one of the options. - draw attention of the administrators to the need to allocate sufficient resources and funding for severe mental disorders, so that the individuals with substance use, their families and the society can benefit and access the treatments.	

4.3. Summary of judgements

Table 11. Summary of judgements

Priority of the problem	- Don't know	- Varies		- No	- Probably No	- Probably Yes	✓ **Yes**
Desirable effects	✓ **Don't know**	- Varies		- Trivial	- Small	✓ **Moderate**	- Large
Undesirable effects	✓ **Don't know**	- Varies		- Large	- Moderate	- Small	- Trivial
Certainty of the evidence	- No included studies			✓ **Very low**	- Low	✓ **Moderate**	- High
Values				- Important uncertainty or variability	- Possibly important uncertainty or variability	✓ **Probably no important uncertainty or variability**	- No important uncertainty or variability
Balance of effects	- Don't know	- Varies	- Favours comparison	- Probably favours comparison	✓ **Does not favour either**	✓ **Probably favours intervention**	- Favours intervention
Resources required	✓ **Don't know**	- Varies	- Large costs	- Moderate costs	- Negligible costs or savings	- Moderate savings	- Large savings
Certainty of the evidence on required resources	✓ **No included studies**			- Very low	- Low	- Moderate	- High
Cost–effectiveness	✓ **No included studies**	- Varies	- Favours comparison	- Probably favours comparison	- Does not favour either	- Probably favours intervention	- Favours intervention
Equity, equality and non-discrimination	- Don't know	- Varies	- Reduced	- Probably reduced	- Probably no impact	✓ **Probably increased**	- Increased
Feasibility	- Don't know	✓ **Varies**		- No	- Probably No	- Probably Yes	- Yes
Human rights and sociocultural acceptability	- Don't know	✓ **Varies**		- No	- Probably No	- Probably Yes	- Yes

✓Indicates category selected, -Indicates category not selected

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Appendix I: Table 1. Studies on carers of persons with schizophrenia/psychosis/schizophrenia spectrum disorder (n=45)

Author(s), country (year)	Sample and design	Intervention/control	Main components of intervention(s)	Assessment instruments	Main results in the experimental group	Global comment
Amaresha et al, India (2018)	N = 80 siblings of persons with schizophrenia (N = 40 experimental intervention; N = 40 control group) Prospective controlled open-label trial	Brief psychoeducation program versus treatment-as-usual	Information about the disorder Drug compliance Expressed emotion Healthy lifestyles Coping strategies Practical support	Knowledge About Schizophrenia Interview (KASI) Affiliate Stigma Scale (self-stigma scale) Burden Assessment Schedule (BAS)	Significant increase in knowledge and reduction in self-stigma with medium effect size.	Positive effect
Ata & Doğan, Turkey (2017)	N = 61 carers (including mothers, fathers, siblings, spouses, others; no specific inclusion criteria) of persons with schizophrenia (N=36 experimental intervention; N=35 control group) Pre-test/post-test	Brief Cognitive Behavioural Stress Management Programme (BCBSMP) versus treatment-as-usual	Stress management techniques Cognitive-behavioural therapy techniques Information about the disorder	General Health Questionnaire-28 (GHQ-28) Stress Self-Assessment Checklist (SIS) Scale of evaluation of coping attitude (COPE) Zarit Caregiver Burden Scale (ZCBS)	Increase in the skills related to problem-focused and emotion-focused coping. Stress indicators and levels of care burden decreased at the end of the intervention.	Positive effect
Brown & Weisman de Mamani, USA (2018)	N = 175 carers (including mothers, fathers, siblings, spouses, others; no specific inclusion criteria) of persons with schizophrenia (N = 98 CIT-S group; N = 77 PSY-ED group)	Culturally Informed Family Therapy for Schizophrenia (CIT-S) versus Family Psychoeducation (PSY-ED)	CIT-S Communication skills Problem-solving Coping strategies PSY-ED	Depression Anxiety and Stress Scale (DASS)	Reduction in individual DASS, from baseline to termination. CIT-S increased family cohesion from baseline to midpoint.	Positive effect

Author(s), country (year)	Sample and design	Intervention/control	Main components of intervention(s)	Assessment instruments	Main results in the experimental group	Global comment
	Randomized controlled trial		Standard sessions of family psychoeducation			
Budiono et al, Indonesia (2021)	N = 64 carers (including mothers, fathers, siblings, spouses, others; no specific inclusion criteria) of persons with schizophrenia (N = 32 experimental intervention; N = 32 control group) Randomized controlled trial	Educational video materials about schizophrenia versus waiting list	Information about the disorder Current therapies Expressed emotion	Illness Perception Questionnaire for Schizophrenia - Relatives (IPQS-R) Five-Minute Speech Samples (FMSS) for evaluating family members' expressed emotion	Positive impact on illness perception and levels of expressed emotion.	Positive effect
Bulut et al, Turkey (2016)	N = 62 carers (including mothers, fathers, siblings, spouses, others; no specific inclusion criteria) of persons with schizophrenia (N = 30 experimental intervention; N = 32 treatment-as-usual group) Pre-test/post-test	Brief group psychoeducation versus treatment-as-usual	Information about the disorder Communication skills Problem-solving techniques Coping strategies	Perceived Family Burden Scale (PFBS)	Significant reduction in perceived family burden.	Positive effect
Chien et al, Hong-Kong (2016)	N = 116 carers (including mothers, fathers, siblings, spouses, others; no specific inclusion criteria) of persons with recent onset psychosis	Self-help problem-solving-based manual-guided self-learning programme (in addition to usual care) versus usual	Problem-solving techniques Information about the disorder	Family Burden Interview Schedule (FBIS) Experience of Caregiving Inventory (ECI)	Significant improvement in ECI score and family burden.	Positive effect

Author(s), country (year)	Sample and design	Intervention/control	Main components of intervention(s)	Assessment instruments	Main results in the experimental group	Global comment
	(N = 58 experimental intervention; N = 58 treatment-as-usual group) Randomized controlled trial	family support service only		Social Problem-Solving Inventory, Revised: Short version (SPSI-R:S)		
Chien et al, Hong-Kong (2018)	N = 201 carers (including mothers, fathers, siblings, spouses, others; no specific inclusion criteria) of persons with recent onset psychosis (N = 70 Family-Led Mutual Support Group; N = 70 psychoeducation; N = 70 control group) Randomized controlled trial	Family-Led Mutual Support Group (FMSG) program (in addition to routine psychiatric outpatient care) versus psychoeducation versus treatment-as-usual	<u>FMSG</u> Information about the disorder Problem-solving techniques Caregiving skill practices <u>Psychoeducation</u> Information about the disorder Psychological support	Family Burden Interview Schedule (FBIS) Family Support Services Index (FSSI) Family Assessment Device (FAD)	Improvement of family functioning and reduction of perceived burden over a long-term follow-up with both interventions.	Positive effect
Chien et al, Hong-Kong (2020)	N = 114 carers (including mothers, fathers, siblings, spouses, others; no specific inclusion criteria) of persons with recent onset psychosis (N = 38 Problem-Solving Based Self-Learning Programme; N = 38 Family Psychoeducation Group Program; N = 38 usual	Problem-Solving Based Self-Learning Programme (PBSP), in addition to usual care (5 months) versus Family Psychoeducation Group Program (FPGP) versus usual psychiatric care and family	<u>PBSP</u> Self-directed cognitive and behavioural process <u>FPGP</u> Information about the disorder Caregiving skills training	Family Burden Interview Schedule (FBIS) Experience of Caregiving Inventory (ECI) Social Problem-Solving Inventory, Revised: Short version (SPSI-R:S)	Improvement in family burden and problem-solving ability.	Positive effect

Author(s), country (year)	Sample and design	Intervention/control	Main components of intervention(s)	Assessment instruments	Main results in the experimental group	Global comment
	psychiatric care) Randomized controlled trial	support	Psychological support			
Chien et al., (China), 2008	N = 76 carers of persons with schizophrenia (N = 38 mutual support; N = 38 control) Randomized controlled trial with a repeated measures design	Peer-Led Mutual Support Group Intervention versus routine family care	Educational component Teaching coping strategies and care-giving skills	Family Burden Interview Schedule (FBIS) Six-Item Social Support Questionnaire (SSQ6)	The family burden score of the mutual support group decreased significantly over 12 months. The satisfaction of social support score of the support group increased significantly	Positive effect
Chien et al., (Hong-Kong), 2004	N = 48 relatives of persons with schizophrenia (N = 24 experimental group; N = 24 control group) Randomized controlled trial	Mutual support group and usual outpatient care versus usual outpatient care	Encouraging mutual support Teaching problem solving skills	Family burden interview schedule (FBIS) Family assessment device (FAD) Family support service index (FSSI)	Family caregivers in the mutual support group experienced a significant reduction in family burden in relation to caring for their relative with schizophrenia	Positive effect
Chien et al., China (2008)	N = 76 carers of persons with schizophrenia (N = 38 mutual support group; N = 38 standard care)	Family-led mutual support group versus standard psychiatric care	Information about mental illness, treatment and community resources Emotional support and empathy	Family Burden Interview Schedule (FBIS) Family Assessment Device (FAD) Six-Item Social Support Questionnaire (SSQ6)	The mutual support group experienced significantly greater improvements in families' burden, functioning and number of support persons	Positive effect

Author(s), country (year)	**Sample and design**	**Intervention/control**	**Main components of intervention(s)**	**Assessment instruments**	**Main results in the experimental group**	**Global comment**
	Randomized controlled trial with a repeated measures design			Family Support Service Index (FSSI)		
Chou et al., (Taiwan), 2002	N = 70 relatives of persons with schizophrenia (N = 35 experimental group; N = 35 control group) Non-equivalent control group design	Professionally lead support group versus no intervention	Information about community resources, financial issues pertaining to mental illness, in-home services and medical needs	Caregiver burden Inventory (CBI) Beck Depression Inventory (BDI) Ad-hoc participants' satisfaction questionnaire Physical Self-Maintenance Scale (PSMS) Instrumental Activities of Daily Living (IADL) Caregiving Self-Efficacy Scale (CSS)	The depression was statistically reduced from the pre-test to the post-test and one-month follow-up. Caregivers' level of perceived burden changed substantially over a 8-week period of support groups and one-month follow-up.	Positive effect
Day et al, Australia (2017)	N = 17 carers (including mothers, fathers, siblings, spouses, others; no specific inclusion criteria) of persons with early psychosis Pre-test/post-test	Journey to Recovery group program	Psychoeducation Support	*Ad-hoc* questionnaire evaluating levels of knowledge in: understanding of psychosis, recovery, medication, relapse prevention, links between substance use and psychosis	Significant improvements in family members' understanding of psychosis, recovery, medication, relapse prevention and substance use comorbidities. Reduction in the levels of isolation and experience	Limited effect

Author(s), country (year)	Sample and design	Intervention/control	Main components of intervention(s)	Assessment instruments	Main results in the experimental group	Global comment
					of stigma.	
de Mamani & Suro, USA (2016)	N = 113 carers (including mothers, fathers, siblings, spouses, others; no specific inclusion criteria) of persons with schizophrenia (N = 64 randomized to CIT-S; N = 49 randomized to PSY-ED) Randomized controlled trial	Family Focused, Culturally-Informed Treatment For Schizophrenia (CIT-S) versus three-session psychoeducation	CIT-S Cognitive behavioural techniques Modules on spirituality and family collectivism Information on the disorder (causes, treatments, consequences)	Shame and guilt/self-blame assessed using Likert ratings that ranged from 1 to 7 Modified Burden Assessment Scale for Families of the Seriously Mentally Ill (BAS)	CIT-S was found to outperform PSY-ED in reducing guilt/self-blame and caregiver burden.	Positive effect
Deane et al, Australia (2015)	N = 81 carers (including mothers, fathers, siblings, spouses, others; no specific inclusion criteria) of persons with psychosis (N = 40 experimental intervention; N= 41 control group) Randomized controlled trial	Connection group (information booklet, followed by 12 recovery-focused interactive newsletters) versus information only	Goal-directed informative booklet, focusing on strengths and promoting personal growth and development	Kessler-10 (K10) Experience of Caregiving Inventory (ECI) Psychological Well-Being (PWB) Adult State Hope Scale (ASHS) Recovery Knowledge Inventory (RKI)	Improvements in distress, hope and negative caregiving experiences over 12 months.	Positive effect
Friedman-Yakoobian et al, USA (2016)	N = 10 carers (including mothers, fathers, siblings, spouses, others; no specific inclusion criteria) of persons with schizophrenia Pre-test/post-test	Family Directed Cognitive Adaptation (including psychoeducation about schizophrenia and related cognitive difficulties; feedback	Psychoeducation Problem-solving techniques	Burden Assessment Scale for Families of the Seriously Mentally Ill (BAS) Client Satisfaction Questionnaire (CSQ)	Significant reduction in burden on the BAS at the end of treatment, which was maintained at follow-up.	Positive effect

Author(s), country (year)	Sample and design	Intervention/control	Main components of intervention(s)	Assessment instruments	Main results in the experimental group	Global comment
		about the client's cognitive strengths and weaknesses; and collaborative identification of cognitive adaptation strategies)				
Gleeson et al, Australia (2017)	N = 29 carers (including mothers, fathers, siblings, spouses, others; no specific inclusion criteria) of persons with first episode psychosis Pre-test/post-test	Moderated Online Social Therapy (MOST)	Self-care Psychoeducation Communication skills Coping strategies	Perceived Stress Scale (PSS) Depression Anxiety and Stress Scale (DASS) Scales of Psychological Well-being Medical Outcomes Study: Social Support Survey (MOS-SSS)	Moderate correlations between reductions in stress and use of the online system. Moderate and significant correlations between degree of improvement in stress and number of log-ons.	Positive effect
Gutiérrez-Maldonado & Caqueo-Urìzar, Chile (2007)	N = 45 caregivers of persons with schizophrenia (N = 22 psycho-educational family intervention group; N= 23 control group) Randomized controlled trial	Psycho-educational family program versus standard intervention	Family's experience of schizophrenia Psycho-education Skills to improve communication Relatives' self-care	Zarit Caregiver Burden Scale (ZCBS) Ad-hoc caregivers' knowledge of schizophrenia questionnaire	Burden decreased significantly in the psychoeducational group	Positive effect
Hamza et al, India (2019)	N = 48 carers (including parents, siblings, spouses, children) of persons with	Self‐help yoga manual associated with visual	Video and photo shoot of yoga procedures	Burden Assessment Scale (BAS) Perceived Stress	No changes in burden, stress and quality of life at the	No effect

Author(s), country (year)	Sample and design	Intervention/control	Main components of intervention(s)	Assessment instruments	Main results in the experimental group	Global comment
	schizophrenia (N = 23 experimental intervention; N = 25 control group) Randomized controlled trial	support (DVD) versus usual care		Scale (PSS) WHO Quality Of Life Scale (WHOQOL-Brief)	end of the intervention.	
Koolaee & Etemdai, Iran (2009)	N = 55 mothers of persons with schizophrenia (N = 18 behavioural family group; N = 19 psychoeducation group; N = 18 standard care Randomized controlled trial	Psychoeducation group versus behavioural family management group versus group receiving standard psychiatric care	Psychoeducation Information on the disorder Problem-solving training Behavioural family management group intervention Information on the disorder Communication skills Standard outpatient care Counselling	Family Burden Interview Schedule (FBIS) Family Questionnaire (FQ)	The perceived burden reduced significantly over time when compared with the score for the behavioural family management grou	Positive effect
Kordas et al, Poland (2015)	N = 13 carers (including parents and siblings) of persons with schizophrenia Pre-test/post-test	Psychoeducation	Information about the disorder Communication skills Psychodrawing	*Ad-hoc* questionnaire including: participants' needs and expectations; knowledge of schizophrenia and its treatment; stress and illness-related	No significant increase in participants' theoretical knowledge on schizophrenia. Reduced subjective sense of	Positive effect

Author(s), country (year)	Sample and design	Intervention/control	Main components of intervention(s)	Assessment instruments	Main results in the experimental group	Global comment
				burden	burden in the family.	
Kumar et al, India (2020)	N = 66 key carers (various) of persons with schizophrenia (N = 33 experimental intervention; N=33 nonspecific control intervention group) Randomized controlled trial	Brief psychosocial intervention, consisting of two sessions of psychoeducation on individual basis, followed by six group therapy sessions, versus general information and support only	Information about the disorder Expressed emotion Problem-solving techniques Coping strategies Communication skills	Burden Assessment Schedule (BAS) WHO Quality Of Life Scale (WHOQOL-100)	Significant reduction in the levels of burden of care and improvement in quality of life.	Positive effect
Leavey et al., 2004 (UK)	N = 106 carers of persons with FEP (N = 57 experimental group; N = 49 control group) Randomized controlled trial	Experimental versus treatment as usual (usual support from the psychiatric service)	Psychoeducation	Verona Service Satisfaction Questionnaire (Relatives) (VSSS-32) Perceived severity of illness Caregiver Strain Index (CSI)	Significant reduction in the levels of strain experienced by carers	Positive effect
Lobban et al, UK (2020)	N = 800 carers (various, no specific inclusion criteria) of persons with either psychosis or bipolar disorder (N = 399 experimental intervention; N = 401 control group)	REACT (psychoeducation modules, peer support through a group forum, confidential messaging and a comprehensive resource directory of	Psychoeducation modules Information about the disorder Stress management	Carer Well-being and Support (CWS) Questionnaire General Health Questionnaire-28 (GHQ-28) Brief Illness Perception Questionnaire (Brief	Significant reduction of distress. Carer well-being and support both increased significantly over time. *(Not possible to separate outcomes*	Positive effect

Author(s), country (year)	Sample and design	Intervention/control	Main components of intervention(s)	Assessment instruments	Main results in the experimental group	Global comment
	Randomized controlled trial	national support) versus access to the same resource directory. All trial participants received treatment as usual		IPQ)	*according to patient's diagnosis)*.	
Martìn-Carrasco et al, Spain (2016)	N = 223 carers (including mothers, fathers, siblings, spouses, others; no specific inclusion criteria) of persons with schizophrenia (N = 109 experimental intervention; N = 114, control group) Randomized controlled trial	Psychoeducational Intervention Program (PIP) versus standard care	Behavioural-cognitive approach Information about the disorder Cognitive strategies for reframing negative emotional responses Healthy lifestyle Stress management	Zarit Burden Interview (ZBI) Involvement Evaluation Questionnaire (IEQ)	Significant reduction of family burden at 4 month and 8 month follow-up.	Positive effect
McCann et al, Australia (2017)	N = 124 carers (mostly parents) of persons with first episode psychosis (N = 61 experimental intervention; N = 63 treatment-as-usual) Randomized controlled trial	Self-help problem-solving bibliotherapy "Reaching Out: Supporting a Family Member or Friend with First-Episode Psychosis"	Information about the disorder Problem-solving techniques Communication skills	Social Problem-Solving Inventory-Revised: Short Form (SPSI-R:S)	Improvement of problem-solving abilities, maintained at both follow-up time points.	Positive effect
McCann et al., Australia (2012)	N = 124 relatives of persons with FEP (N = 61,bibliotherapy; N =	Problem-Solving Bibliotherapy Intervention (PSBI) versus treatment as	Problem-solving based bibliotherapy Information on strengthening the	Experience of Caregiving Inventory (ECI) Kessler Psychological	The PSBI group experienced a greater reduction in negative emotional	Positive effect

Author(s), country (year)	Sample and design	Intervention/control	Main components of intervention(s)	Assessment instruments	Main results in the experimental group	Global comment
	63, treatment as usual) Randomized controlled trial	usual (specialist support, coordinated by a case manager and psychiatrist)	carer's well-being (physical and mental) and coping skills	Distress Scale (K10) Family Questionnaire (FQ) Short Form Health Survey (SF-12)	evaluations of the need to provide additional support to young people with FEP than the TAU group by week 6, while the level of psychological distress decreased at a greater rate from baseline to 6 weeks in the PSBI compared with the TAU group.	
Mubin et al, Indonesia (2019)	N = 84 carers (various, no specific inclusion criteria) of persons with schizophrenia (N = 42 experimental intervention; N = 42 control group) Randomized controlled trial	Psychoeducation versus standard educational care	Information about the disorder Stress management Coping strategies	Indonesian version of Care Burden Scale (CBS)	Significant reduction of family burden.	Positive effect
Ngoc et al, Vietnam (2016)	N = 59 carers (various, no specific inclusion criteria) of persons with schizophrenia (N = 30 experimental intervention; N = 29 control group) Randomized controlled trial	Family Schizophrenia Psychoeducation Program (FSPP) versus treatment-as-usual	Information about the disorder Problem-solving techniques Communication skills	Quality of Life Enjoyment and Satisfaction Questionnaire (QLESQ) Stigma Towards Schizophrenia Scale developed for Vietnamese patients	Significant reduction in family-reported stigma and quality of life, with effect sizes from moderate to large.	Positive effect

Author(s), country (year)	Sample and design	Intervention/control	Main components of intervention(s)	Assessment instruments	Main results in the experimental group	Global comment
				(STSS) Ad-hoc questionnaire for evaluating consumer satisfaction		
Öksüz et al, Turkey (2017)	N = 60 carers (including parents, siblings and spouses; no specific inclusion criteria) of persons with first episode psychosis (N = 30 experimental intervention; N = 30 control group) "Quasi-experimental design with control group"	Psychoeducation versus treatment-as-usual	Information about the disorder Communication skills	Expressed Emotion Scale (EES) Family Assessment Device (FAD)	Decrease of expressed emotion (such as criticism/hostility and overinvolvement-protecting), improvement in family functioning.	Positive effect
Posner et al., (Canada) 1992	N = 55 family members of persons with schizophrenia (N = 28 experimental condition; N = 27 control condition) Randomized controlled trial	Psychoeducation support-group program versus waiting list	Psychoeducational approach including educational component; coping strategies, problem solving and communication skills	Schizophrenia Knowledge Test (SKT) Consumer Satisfaction Questionnaire (CSQ) Family Satisfaction Scale (FSS) Negative Feelings for Patients Ways of coping (WOC)	Carers reported a significant improvement in the levels of knowledge on the illness and reported a more positive evaluation of health care services. No significant change in levels of coping strategies, family	Positive effect only on levels of burden

Author(s), country (year)	Sample and design	Intervention/control	Main components of intervention(s)	Assessment instruments	Main results in the experimental group	Global comment
				General Health Questionnaire (GHQ)	satisfaction and well-being were found.	
Puspitosari et al, Indonesia (2019)	N = 100 carers (including mothers, fathers, siblings, spouses, others; no specific inclusion criteria) of persons with schizophrenia (N = 50 experimental intervention; N = 50 control group) "Quasi-experimental study"	Psychoeducation and social skills training versus routine outpatient care	Psychoeducation Social skills training Stress management Communication skills	Quality of Life Interview (QOLI)	Improvement in quality of life.	Positive effect
Rami et al, Egypt (2018)	N = 50 carers (first degree relatives) of persons with schizophrenia (N = 26 experimental intervention; N = 24 control group) Randomized controlled trial	Behavioural Family Psycho-Educational Program (BFPEP) versus treatment-as-usual	Psychoeducation Communication enhancement training Skills for active listening Problem-solving	Social Functioning Questionnaire (SFQ) Quality of Life Scale (QLS) Drug Attitude Inventory (DAI)	Improvement in the levels of social functioning, attitudes towards medication, and quality of life.	Positive effect
Sharif et al., (Iran), 2012	N =70 caregivers of persons with schizophrenia (N = 35 experimental group; N = 35 control groups) Randomized controlled trial	Psychoeducational intervention versus no intervention	Psychoeducational approach	Family Burden Questionnaire (FBQ)	Positive effects in reduction of family burden immediately and one month after the intervention.	Positive effect
Sharma et al, India (2021)	N = 40 carers (including mothers, fathers, daughters, sons, spouses, siblings; no specific inclusion criteria) of	Psychoeducation versus no intervention	Information about the disorder Communication skills Expressed emotion	Ryff Psychological Well-being (PWB) scale	Significant improvement in emotional regulation and in levels of personal well-being.	Positive effect

Author(s), country (year)	Sample and design	Intervention/control	Main components of intervention(s)	Assessment instruments	Main results in the experimental group	Global comment
	persons with schizophrenia (N = 20 experimental intervention; N = 20 control group) Randomized controlled trial					
Shiraishi et al, Japan (2019)	N = 74 carers (including mothers, fathers, spouses, siblings; no specific inclusion criteria) of persons with recent onset or chronic psychosis (N = 37 experimental intervention plus treatment-as-usual; N = 37 treatment-as-usual only) Randomized controlled trial	Standard Model of Family Psychoeducation (SM-FPE) versus treatment-as-usual	Information about the disorder Communication skills Problem-solving	Japanese version of Zarit Burden Interview Short version (J-ZBI-8) Family Accommodation Scale (FAS) Link's Stigma Scale (LSS)	No effects on anxiety, family burden and levels of expressed emotions.	No effect
Smeerdijk et al, The Netherlands (2015)	N = 97 carers (parents) of persons with schizophrenia (N = 53 experimental intervention; N = 47 control group) Randomized controlled trial	Psychoeducation followed by either Family Motivational Intervention (FMI) or Routine Family Support (RFS) versus RFS only	Psychoeducation Problem-solving techniques Motivational interview	Experience of Caregiving Inventory (ECI) Family Questionnaire (FQ) General Health Questionnaire (GHQ-28)	Both groups improved in parental distress and sense of burden. Only in the FMI group, a further decrease of parental distress was observed from 3 month to 15 month follow-up.	Positive effect
So et al, Hong-Kong, (2006)	N = 55 carers of people with FEP	Experimental intervention versus waiting list control	Knowledge about psychosis, skills in handling	Level of Expressed Emotion (LEE) Knowledge about	Carers significantly improved levels of knowledge about	Positive effect

Author(s), country (year)	Sample and design	Intervention/control	Main components of intervention(s)	Assessment instruments	Main results in the experimental group	Global comment
	(N = 22 experimental group; N = 23 control group) Randomized controlled trial	condition	the patients' illness and their own caregiving stress; stress management, communication skills, and relapse prevention	psychosis scale Experience of Caregiving Inventory (ECI) Chinese Ways of Coping Questionnaire (CWCQ) Life Events Questionnaire (LEQ)	psychosis	
Szmukler et al., (Australia), 1996	N = 63 carers of persons with schizophrenia (N = 32 Intervention group; N = 31 Control group) Randomized controlled trial	Experimental intervention: counselling Control condition: information about the illness and services	Educational component Teaching of coping Strategies	General Health Questionnaire (GHQ) Assessment of physical status Positive and Negative Affects Scale Experience of Caregiving Inventory (ECI) Mastery	Carers reported a better understanding of the patient and in the perception of a more positive relationship. No significant difference was found between the groups for global physical health.	Positive effects only on levels of knowledge
Szmukler et al., (Australia), 2003	N = 61 carers of persons with psychosis (N = 30 experimental intervention; N = 31, standard care) Randomized controlled trial	Experimental intervention versus control condition	Experimental intervention: counselling including educational and problem-solving components Control intervention: single counselling session	Experience of Caregiving Inventory (ECI) Ways of Coping (WOC) Mastery	A small effect in enhancing positive aspects of the relationship with the patient and a stronger effect in helping the relative understand the patient's illness better were found	Slight positive effect

Author(s), country (year)	Sample and design	Intervention/control	Main components of intervention(s)	Assessment instruments	Main results in the experimental group	Global comment
Verma et al, India (2019)	N = 30 carers (first degree relatives) of persons with schizophrenia (N = 15 experimental intervention; N = 15 control group) Pre-test/post-test	Family psychoeducation versus no intervention	Information about the disorder Expressed emotion	WHO Quality Of Life Scale (WHO-QOL-Brief)	Improvement in quality of life.	Limited effect
Zhou et al, Hong Kong (2020a)	N = 89 carers (including parents, siblings and spouses; no specific inclusion criteria) of persons with schizophrenia (N = 46 experimental intervention; N = 43 control group) Randomized controlled trial	Collective Narrative Therapy Groups (CNTG) versus waiting list	Experiential learning Role play Discussion of difficulties	Brief Family Relationship Scale (BFRS) Experience of Caregiving Inventory (ECI-66) Mental Health Inventory (MHI-5): mental well-being	Improvement in family relationship, caregiving experiences, inner resources, hope, mental health status and caregiving burden.	Positive effect
Zhou et al, Hong Kong (2020b)	N = 132 carers (including parents, siblings and spouses; no specific inclusion criteria) of persons with schizophrenia (N = 29 psychoeducation; N = 34 narrative therapy; N = 31 control group) Randomized controlled trial	FamilyLink Education Program (FLEP), a peer-led psychoeducational program, versus narrative-based intervention versus waiting list	Information about the disorder Coping strategies Communication skills Storytelling of personal experiences	Brief Family Relationship Scale (BFRS) Experience of Caregiving Inventory (ECI) Family Coping Questionnaire (FCQ) Mental Health Inventory (MHI) Pearline Mastery Scale (PMS)	Improvement of caregiving burden in both intervention groups.	Positive effect

Appendix I: Table 2. Studies on carers of persons with bipolar disorder (n=15)

Author(s), country (year)	Sample and design	Intervention	Main components of intervention(s)	Assessment instruments	Main results in the experimental group	Global comment
Abad et al, Iran (2021)	N = 60 wives (N = 30 experimental intervention; N = 30 control group) Randomized controlled trial	Problem-solving skills training versus psychological support	Problem-solving techniques Brain storming	Index of Spouse Abuse	Significant changes in abuse scores (physical, non-physical and total scores).	Positive effect
Barbeito et al, Spain (2021)	N = 148 carers (various; no specific inclusion criteria) (N = 74 experimental intervention; N = 74 control group) Randomized controlled trial	Multifamily psychoeducational program versus control group discussing general topic	Psychoeducation Problem-solving techniques	Family Burden Self-Report (FB-SR) scale Strauss-Carpenter Scale (SCS)	Significant improvement in objective and subjective family burden.	Positive effect
de Souza et al, Brazil (2016)	N = 53 carers (including mothers, partners or others; no specific inclusion criteria) (N = 25 experimental intervention; N = 28 control group) Randomized controlled trial	Psychoeducational intervention versus sessions with the caregiver without any specific intervention	Information about the disorder Stress management Early warning signs	Family Burden Interview Schedule (FBIS) Rosenberg Self-Esteem Scale (RSS) Health Survey-36-Item Short Form (SF-36)	No significant improvement in levels of burden, self-esteem and quality of life.	No effect

Fiorillo et al, Italy (2015)	N = 155 carers (including parents, spouses/significant others; no specific inclusion criteria) (N = 85 experimental intervention; N = 70 control group) Randomized controlled trial	Psychoeducational family intervention versus waiting list	Information about the disorder Problem-solving techniques Communication skills	Social Network Questionnaire (SNQ) Family Problem Questionnaire (FPQ)	Significant reduction of relatives' objective and subjective burden.	Positive effect
Gex-Fabry et al, Switzerland (2015)	N = 26 carers (including partners, fathers, mothers, brothers, sisters; no specific inclusion criteria) Pre-test/post-test study	Group psychoeducation	Information on the disorder and its treatment Problem-solving techniques	World Health Organization Quality of Life questionnaire (WHOQOL-BREF)	Benefits in detecting the early warning signs of relapse, improvement of quality of life, feeling more involved in caregiving activities.	Positive effect
Hubbard et al, Australia (2016)	N = 32 carers (including partners, parents, siblings, friends; no specific inclusion criteria) (N = 14 experimental intervention; N = 18 waiting list) Randomized clinical trial	Brief, two-session psychoeducational intervention for caregivers versus waiting list	Psychoeducation Coping strategies Communication skills Problem-solving techniques	Depression Anxiety and Stress Scale (DASS-21) Burden Assessment Scale (BAS) *Ad-hoc* scale on knowledge of bipolar disorder *Ad-hoc* scale on bipolar disorder self-efficacy	Significant reductions in burden, improvement in self-efficacy and knowledge.	Positive effect

Lobban et al, UK (2020)	N = 800 carers (various, no specific inclusion criteria) (N = 399, experimental intervention; N = 401, control group) Randomized controlled trial	REACT (psychoeducation modules, peer support through a group forum, confidential messaging and a comprehensive resource directory of national support) versus access to the same resource directory. All trial participants received treatment as usual	Information about the disorder Stress management	Carer Well-being and Support (CWS) Questionnaire General Health Questionnaire-28 (GHQ-28) Brief Illness Perception Questionnaire (Brief IPQ) Brief Coping Orientation to Problems Experienced inventory (Brief COPE)	Significant reduction of distress. Carer well-being and support both increased significantly over time. *(Not possible to separate outcomes according to patient's diagnosis)*.	Positive effect
Luciano et al, Italy (2015)	N = 155 carers (including parents, spouses/significant others; no specific inclusion criteria) (N = 85 experimental intervention; N = 70 control group) Randomized controlled trial	Psychoeducational family intervention versus waiting list	Information about the disorder Problem-solving techniques Communication skills	Social Network Questionnaire (SNQ) Family Problem Questionnaire (FPQ)	Reduction in objective and subjective family burden.	Positive effect

Madigan et al., Ireland (2012)	N = 47 carers of persons with bipolar disorder (N = 18 Multi Family Group Psychoeducation; N = 19 Solution Focused Group Psychotherapy; N = 10 Treatment as Usual) Randomized controlled trial	Multifamily Group Psychoeducation (MFGP) versus Solution Focussed Group Psychotherapy (SFGP) versus Treatment as usual (TAU)	MFGP Psychoeducation SFGP Teaching of problem- solving strategies	Knowledge of Illness Questionnaire (KOIQ) Involvement Evaluation Questionnaire (IEQ) General Health Questionnaire (GHQ12) Quality of Life (WHOQOL Bref)	Carers in both the MFGP intervention and the SFGP arm demonstrated greater knowledge and reduction in burden.	Positive effect
O'Donnell et al, USA (2020)	N = 145 carers (various; no specific inclusion criteria) (N = 72 experimental intervention; N = 72 control group) Randomized controlled trial	Psychoeducation, communication training, and problem-solving skills training versus enhanced care (briefer psychoeducational treatment)	Information about the disorder Communication skills Problem-solving techniques	Family Adaptability and Cohesion Evaluation Scale (FACES-II) Conflict Behaviour Questionnaire (CBQ)	Increase in family cohesion and adaptability and decrease in family conflict.	Positive effect
Perlick et al, USA (2018)	N = 46 carers (including parents, spouses/significant others, children, friends; no specific inclusion criteria) (N = 25 experimental intervention; N = 21 control group) Randomized controlled trial	Caregiver-only adaptation of family-focused treatment (FFT) versus sessions of standard health education	Psychoeducation and goal setting Behavioural analysis of self-care barriers Cognitive behavioural therapy Problem-solving techniques	Social Behaviour Assessment Scale (SBAS) Health Risk Behaviour Scale (HRB)	Improvement of depressive symptoms, overall psychological health and levels of burden.	Positive effect

Reinares et al, Spain (2004)	N = 45 carers of persons with bipolar I or II disorder (N = 30 experimental group; N = 15 control group) Randomized controlled trial	Psychoeducational Family Intervention versus no treatment	Psychoeducational family intervention Structured information about the disorder Teaching of coping strategies	Social Behaviour Assessment Schedule (for family burden) Family Environment Scale Bipolar Disorder Knowledge Questionnaire	No significant changes were found in the objective burden nor in the relationships within the family environment. Improvement in caregivers' knowledge of bipolar disorder	Some effect only on knowldege
Reupert et al, Australia (2018)	N = 31 children (aged 18-25 years) with a parent having mental illness and/or substance use disorder Pre-test/post-test	Online intervention ("mi.spot") targeting cognitive reappraisal, connectedness to others, and resilience	Information about the disorder Coping strategies	Mental Health Continuum Short Form (MHC-SF) Depression Anxiety and Stress Scale (DASS-21) Coping Orientation to Problems Experienced (COPE) inventory General Help-Seeking Questionnaire (GHSQ) Social Connectedness Scale (SCS) Mental Health Literacy Scale (MHLS) General Self-Efficacy Scale (GSE)	Improvement in depressive symptoms, stress levels, well-being and autonomy. *(Not possible to separate outcomes according to patient's diagnosis)*.	Positive effect

Sampogna et al, Italy (2018)	N = 139 carers (including parents, spouses/significant others; no specific inclusion criteria) (N = 72 experimental intervention; N = 67 control group) Randomized controlled trial	Psychoeducational family intervention versus waiting list	Information about the disorder Problem-solving techniques Communication skills	Family Coping Questionnaire (FCQ)	Improvement in problem-oriented coping strategies, such as positive communication strategy.	Positive effect
Zyto et al, Netherlands (2020)	N = 88 carers (including parents, spouses, others; no specific inclusion criteria) Pre-test/post-test	Psychoeducational program	Psychoeducation Information about the disorder	Level of Expressed Emotion (LEE)	Significant reduction in expressed emotion.	Positive effect

Appendix 1. Table 3. Studies on carers of persons with substance use disorder (n=4)

Author(s), country (year)	Sample and design	Intervention	Main components of intervention(s)	Assessment instruments	Main results in the experimental group	Global comment
Karimi et al, Iran (2019)	N = 80 spouses (N = 40 experimental intervention; N = 40 control group) Randomized controlled trial	Supportive-educational intervention versus control group not receiving any training	Quality of life therapy	Depression Anxiety and Stress Scale (DASS-21) Satisfaction with Life Scale (SWLS)	Improvement in the levels of life satisfaction.	Positive effect
Hojjat et al, Iran (2016)	N = 48 wives (N = 23 experimental intervention; N = 25 control group) Pre-test/post-test	Educational group programme versus waiting list	Information about disorder and its treatment Harm reduction Relapse prevention	ENRICH (Evaluation and Nurturing Relationship Issues, Communication, and Happiness) Marital Satisfaction (EMS) Scale – short form	Improvement in the levels of marital satisfaction.	Positive effect
Osilla et al, USA (2017)	N = 312 spouses (N = 162 experimental intervention; N = 150 control condition) Randomized controlled trial	Partners Connect (web-based intervention using behavioural skills such as self-care and healthy communication) versus waiting list	Motivational interviewing Cognitive behavioural therapy strategies Self-care skills	Social Support Survey (SSS) Family Environment Scale (FES)	Reduction in levels of anxiety and improvement in levels of emotional/informational and social support at follow-up.	Positive effect
Reupert et al, Australia (2018)	N = 31 children (aged 18-25 years) with a parent having mental	Online intervention ("mi.spot") targeting	Information about the disorder Coping	Mental Health Continuum short form (MHC-SF) Depression Anxiety and	Improvement in depressive symptoms, stress levels, well-being and autonomy.	Positive effect

	illness and/or substance use disorder Pre-test/post-test	cognitive reappraisal, connectedness to others, and resilience	strategies	Stress Scale (DASS-21) Coping Orientation to Problems Experienced (COPE) inventory General Help-Seeking Questionnaire (GHSQ) Social Connectedness Scale (SCS) Mental Health Literacy Scale (MHLS) General Self-Efficacy Scale (GSE)	*(Not possible to separate outcomes according to patient's diagnosis)*.	

Appendix II: mhGAP process note

mhGAP Guideline Update: Notes on process for identifying level of evidence review required v2_0 (13/12/2021)

This document is intended to provide guidance to focal points on the level of evidence review required as part of the evidence retrieval process for the mhGAP guideline update process. As a general rule, the update process should be informed by existing high quality systematic reviews.

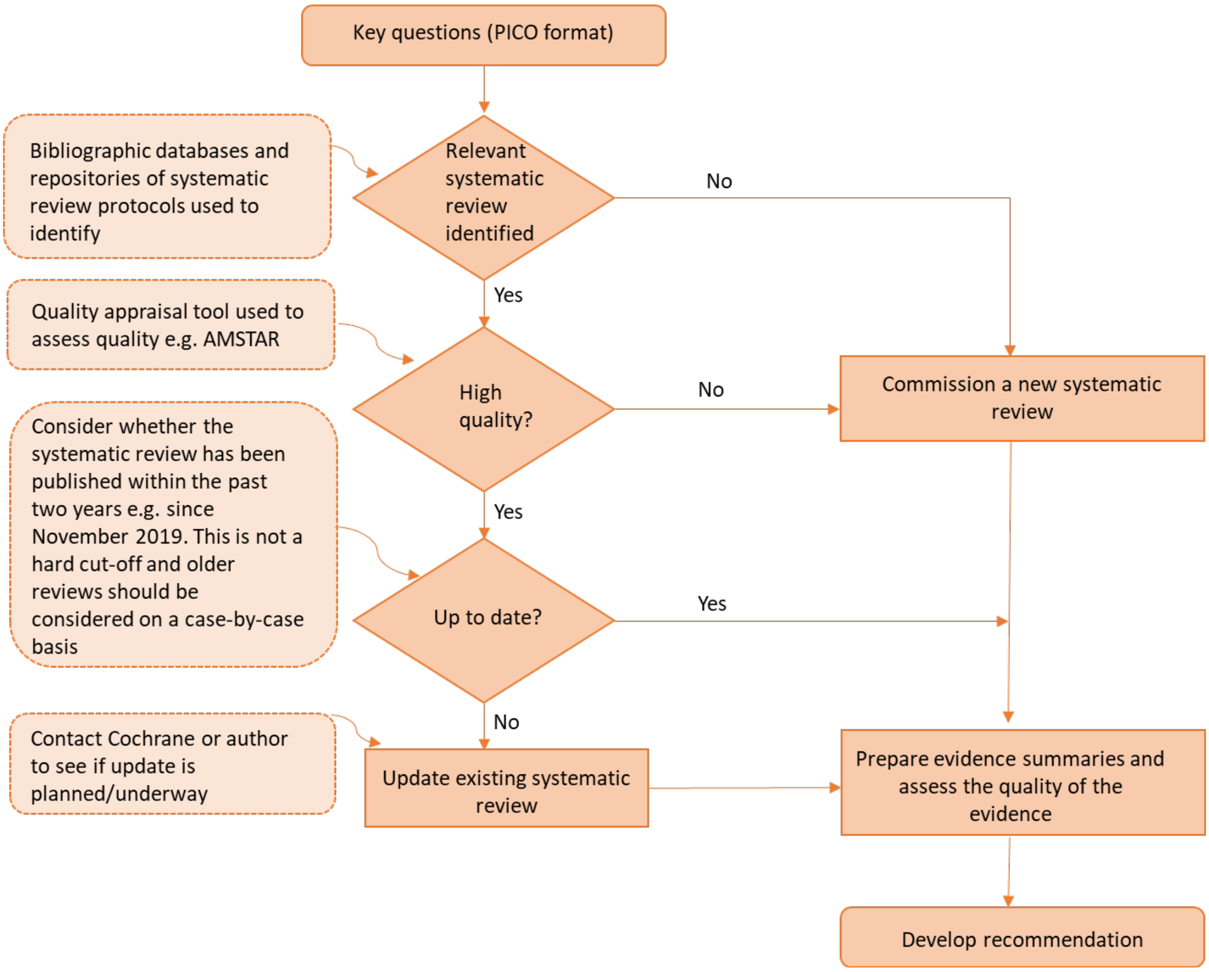
The process for evidence retrieval and synthesis is fully outlined in chapter 8 of the WHO handbook for guideline development https://apps.who.int/iris/handle/10665/145714.

Three main categories of evidence review are proposed in this document:

1) Existing relevant, up to date, high quality systematic review(s) provide the evidence required. **An existing systematic review is sufficient to prepare the evidence summaries**. It may be possible to include more than one systematic review for the same PICO, as different reviews may match different outcomes of a PICO. However, if more than one systematic review is available for the same PICO outcome, one review should be selected, based on quality, relevance, search comprehensiveness and date of last update. The selection process should be transparently reported, with justification of choices.
2) Existing high quality systematic reviews are either out of date or do not fully address the PICO, though it is considered that the review can be updated to meet these requirements. **An update of an existing systematic review is required before the evidence summaries can be prepared**. The update process may require addition of new studies published after the review, or inclusion of outcomes not covered by the existing reviews.
3) Existing systematic reviews are either not of sufficiently high quality or cannot be updated to fully address the PICO. **A new systematic review is required before the evidence summaries can be prepared**

Figure 1 below details the process to identify which level of evidence review is required tosupport the evidence retrieval process for a PICO.

Fig. 1. Is a new systematic review needed



All key questions are currently in PICO format as presented in the Appendix of the planning proposal PICOs. Subsequent steps include the following:

1. **Identify and evaluate existing systematic reviews**: Identify one or more systematic review(s) to address each PICO question. Existing systematic reviews will inform the guideline development process, whether or not a new systematic review or an update of an existing review is required, and the evidence review team will detail existing systematic reviews in each case. The method for identifying existing systematic reviews should be fully detailed in the evidence summary and include the following sources:
    a. Search of bibliographic databases, such as PubMed/MEDLINE, Embase, PsycInfo, Cochrane Central Register of Controlled Trials (CENTRAL), CINAHIL, Scopus, African Index Medicus, Index Medicus for the Eastern Mediterranean Region, Index Medicus for the South-East Asian Region, Latin American and Caribbean Health Sciences Literature, and Western Pacific Region Index Medicus.
    b. Search of repositories of systematic reviews protocols, including PROSPERO, Open Science Framework (OSF), and Cochrane.
2. **Assess if systematic review is up to date:** It is preferred that identified systematic reviews have been published within the past two years e.g. since November 2019. This is not a hard cut-off and older reviews should be considered on a case-by-case basis,

particularly those covering the time period since the last update of the mhGAP guideline in 2015. It is acknowledged that COVID has led to a pausing of many mental health research activities over the past two years, and this may also impact the availability of systematic reviews within the preferred two year period. For any reviews that fall outside the two year period, the guideline methodologist will advise on suitability.

3. **Appraise quality of systematic review:** Use the AMSTAR-2 quality appraisal tool to assess the quality of the identified systematic review(s) https://amstar.ca/docs/AMSTAR-2.pdf . This includes consideration of the extent to which the PICO is fully addressed by the systematic review(s) identified.

By following the process outlined in figure 1, and steps 1-3 above, the FP and evidence review team will have sufficient evidence to assess which of the three main categories of evidence review apply to each PICO under consideration:

1) Existing systematic reviews are sufficient to prepare the evidence summaries
2) An update of an existing systematic review is required before the evidence summaries can be prepared
3) A new systematic review is required before the evidence summaries can be prepared