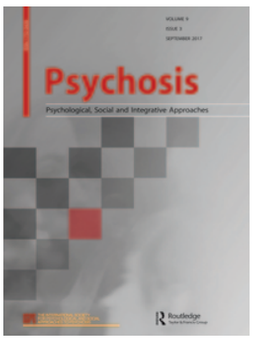

Routledge
Taylor & Francis Group

Psychosis

Psychological, Social and Integrative Approaches

ISSN: 1752-2439 (Print) 1752-2447 (Online) Journal homepage: https://www.tandfonline.com/loi/rpsy20

A manualised treatment protocol to guide delivery of evidence-based cognitive therapy for people with distressing psychosis: learning from clinical trials

Anthony P. Morrison

To cite this article: Anthony P. Morrison (2017) A manualised treatment protocol to guide delivery of evidence-based cognitive therapy for people with distressing psychosis: learning from clinical trials, Psychosis, 9:3, 271-281, DOI: 10.1080/17522439.2017.1295098

To link to this article: https://doi.org/10.1080/17522439.2017.1295098

PSYCHOSIS, 2017
VOL. 9, NO. 3, 271–281
https://doi.org/10.1080/17522439.2017.1295098

Routledge
Taylor & Francis Group

A manualised treatment protocol to guide delivery of evidence-based cognitive therapy for people with distressing psychosis: learning from clinical trials

Anthony P. Morrison[a,b]

[a]Division of Psychology and Mental Health, University of Manchester, Manchester, UK; [b]Psychosis Research Unit, Greater Manchester West NHS Trust, Manchester, UK

ABSTRACT

NICE guidelines recommend use of treatment protocols that have trial-based evidence of efficacy to guide the delivery of CBT for psychosis. The rationale for using such an approach, and a manual that has been used to ensure fidelity and adherence within six clinical trials, is described. The protocol emphasises principles and values, such as collaborative teamwork, active participation involving between session tasks for service users and therapists and a normalising philosophy, as well as specific milestones such as early agreement of a shared goal, maintenance formulations and use of defined change strategies. Challenges to implementation and methods for promoting good practice are considered and implications for future research and practice are discussed.

ARTICLE HISTORY
Received 22 November 2016
Accepted 10 February 2017

KEYWORDS
Cognitive behaviour therapy; Schizophrenia; Treatment guidelines; Treatment outcome research

Rationale for following a protocolised manual

There are several advantages to delivering cognitive behaviour therapy for psychosis (CBTp) in a manner that is consistent with a manualised protocol that has been evaluated in clinical research. The NICE guideline recommendations for CBTp for both young people (National Institute for Clinical Excellence, 2013) and adults (National Institute for Health & Care Excellence, 2014) require it to be based on such a protocol. The competency framework for CBTp (Roth & Pilling, 2013) was developed on the basis of published manuals that have been used in the clinical trials; the likelihood of replicating the outcomes observed in the trials should be maxmised if there is adherence and fidelity to the models and manualised protocols used in such trials (see recent meta-analyses for a comprehensive review of the CBTp trials e.g. (Jauhar et al., 2014; van der Gaag, Valmaggia, & Smit, 2014)).

Within the randomised controlled trials, especially the larger multi-centre studies, the ability to standardise delivery is enhanced by adherence to a protocol, which minimises site differences and increases generalisability. This has led to the development of treatment protocols and use of strategies to monitor adherence and fidelity, such as monitoring of therapy content and milestones using session records and the rating of competence using scales such as the CTSR (Blackburn et al., 2001).

Evidence from a variety of sources suggests that delivering CBTp that adheres to protocols is related to positive outcomes. For example, expert consensus established using the Delphi process suggests that there is agreement regarding the importance of principles, models, formulation, change strategies, homework and therapists' assumptions (Morrison & Barratt, 2010). It is clear from qualitative studies

CONTACT Anthony P. Morrison tony.morrison@manchester.ac.uk

that service users who have received CBTp also agree that factors such as choice, collaboration, normalisation, evaluation of thinking and behaviour, use of formulations and active involvement in tasks between sessions are also seen as valuable components from their perspective (Kilbride et al., 2013). More recently, there is data from large clinical trials suggesting that such components (specifically, agreed goals, formulation, active change strategies and homework) significantly contribute to better outcomes. For example, data from a trial of CBT for people at risk of psychosis demonstrated that there is a greater treatment effect if formulation and homework are involved in therapy, although the high correlation between such components suggests that these may be indicators of overall treatment fidelity (Flach et al., 2015). Also, in a recent trial of CBT for people with psychosis, participants derived benefit if they received full therapy that involved active change strategies such as evaluation of beliefs and the use of behavioural experiments, whereas CBT was potentially harmful if participants received partial therapy that only involved engagement and assessment (Dunn et al., 2012).

This paper will outline a manualised treatment protocol that has been evaluated in six different clinical trials (with over 1000 participants in total). These default assumptions oregarding the process and content of CBTp have been developed over two decades, starting with the IMPACT effectiveness study, which demonstrated that CBTp can achieve good clinical outcomes when delivered in a routine CMHT setting (Morrison et al., 2004b). They were further developed for both the EDIE (Morrison et al., 2004a) and EDIE-2 trials (Morrison et al., 2012), which contributed to the evidence that CBT can improve symptoms and reduce likelihood of transition to psychosis in people at high risk (Stafford, Jackson, Mayo-Wilson, Morrison, & Kendall, 2013). More recently, they were adapted for the ACTION trial (Morrison et al., 2014), which suggested that CBTp may be beneficial for people who have chosen not to take antipsychotic medication. Finally, similar guidelines are currently being evaluated in the COMPARE trial, which is comparing CBT directly with antipsychotics, and the FOCUS trial (Pyle et al., 2016), which is evaluating the approach in people who have not had an adequate response to clozapine (often referred to as "treatment-resistant schizophrenia"). While these clinical trials have worked with different populations (from those at high risk and first episode psychosis through CMHT and treatment-resistant), the basic approach within the protocol is similar. There may be variation in the expected length of treatment, the pace at which milestones such as developing a shared goal or maintenance formulation will be achieved, or the likelihood that certain problems or rate-limiting factors may occur. These will be outlined at various points in the protocol. However, there is much more consistency than difference, regardless of the specific trial.

Overview of the protocol

Overall, the default aim has been to offer up to 30 hours of therapy (up to 26 hours over the first 6–9 months, plus up to four boosters over subsequent 6–12 months). The shorter of these ranges (6 months) has been used for ARMS and FEP trials where there are less iatrogenic difficulties, people may have been functioning well until relatively recently, and there are reasons to try to achieve quick gains (for example, attempting to reduce distress, maintain social or occupational/educational functioning or to prevent an imminent first episode); the longer range (9 months for therapy and 12 months for boosters) have been used for people with more established difficulties with a longer history of problems and service use. However, these guidelines are intended to be used flexibly, and may change in response to client characteristics. There is a recognition that within each population there will be considerable variance in number of sessions, frequency of sessions and pacing within sessions that is required, as well as the rate at which milestones are achieved; however, within the trials, any drift from protocol is prioritised for discussion in supervision and kept to a minimum without clear justification.

In order to ensure competent delivery and adherence and fidelity to the model and protocol of therapy, it is expected that the sessions will be scored as competent on the CTSR and that the trial therapists will complete an electronic session record after each session. Within the protocol, the model and formulations are based on a specific cognitive model (Morrison, 2001) and included change strategies are predominantly drawn from our research team's CBT for psychosis books (French & Morrison,

2004; Morrison, Renton, Dunn, Williams, & Bentall, 2003; Morrison, Renton, French, & Bentall, 2008), but can be supplemented with strategies from other CBTp manuals (e.g. (Fowler, Garety, & Kuipers, 1995; Kingdon & Turkington, 2005). Similarly, if people prioritise non-psychotic difficulties, such as social anxiety, post-traumatic stress or panic attacks, for which compatible cognitive models exist (since the specific model of psychosis was based on an integration of the processes involved in development and maintenance of emotional disorders), then the relevant model will be used to inform situation specific formulations (e.g. (Clark, 1986; Clark & Wells, 1995; Ehlers & Clark, 2000; Wells, 1995)). Change strategies are excluded if inconsistent with the model (e.g. compassion focussed therapy/3 drive systems formulations, mindfulness, acceptance and commitment therapy/hexaflex formulations and motivational interviewing). This is to ensure that the trials evaluate a version of CBTp that is clearly based on the theoretical model and allows such an approach to be clearly defined and replicated. If replicated within routine clinical practice, this should increase the likelihood that the outcomes achieved will match those from the evidence on which the guideline recommendations are based. This should be true even for clinical services that work with populations characterised by complexity (e.g. early intervention services), since the trials have had broad inclusion criteria and few exclusion criteria, and the therapy delivered in these trials has often focused on common problems that are not directly related to psychosis (e.g. anxiety disorders, trauma, substance use, mood, self-harm, relationships).

Principles and values within the protocol

The protocol specifies some clearly defined principles and values, which underpin the use of the more technical elements and change strategies. These are described in detail elsewhere (Brabban, Byrne, Longden, & Morrison, 2016), but include an emphasis on recovery-orientated values, optimism, a good therapeutic relationship, person centred practice (including warmth, empathy and non-judgemental stance), active listening and validation of experiences (the description of the protocol outlined in this article is intended to be utilised alongside the article outlining the principles and values of CBTp (Brabban et al., 2016)). These values are reflected in many of the CTSR items, such as interpersonal effectiveness, appropriate pacing, collaboration, guided discovery and two-way feedback. The principles of CBTp emphasised within this specific protocol are briefly outlined below:

A shared goal is required, since CBTp is collaborative and problem-orientated: this is ensured by not progressing beyond the assessment and engagement phase without establishing a shared goal that is agreed upon by service user and therapist as both meaningful and achievable.

Collaboration is central to good CBTp: this can be achieved in a variety of ways, including regular feedback, teamwork (including agreeing between session tasks for therapists as well as service users), regular reviewing of goals, and use of the theory A – theory B approach (e.g. either you are being persecuted by MI5 or you believe you are being persecuted; either way makes sense of how you feel and what you are doing; can we work together to find out what is going on).

A normalising approach is required that validates the person's experience and does not pathologise psychosis, recognising the validity of the continuum model: this is achieved by the delivery of information regarding the high prevalence of psychotic experiences in non-clinical populations, famous people who have experienced psychosis, personal stories emphasising recovery, positive aspects of psychosis, and common psychosocial causes. The language used in discussing formulations (e.g. given that you think … it is understandable that you feel …; if I believed … then I would feel …; given that … happened to you, it is not surprising that you see yourself as …).

Much of the change-focused work attempts to help people reach their goals by *evaluating how accurate their appraisals are or how helpful their appraisals are*. This can include both verbal reattribution techniques and behavioural experiments.

Effective change-focused work also involves *evaluating the helpfulness of cognitive and behavioural responses*, including the use of behavioural experiments to test out alternative responses.

Active involvement and choice in the change process is required from the service user and should be empowering: this can be achieved by goal setting, conducting between session tasks, involvement in

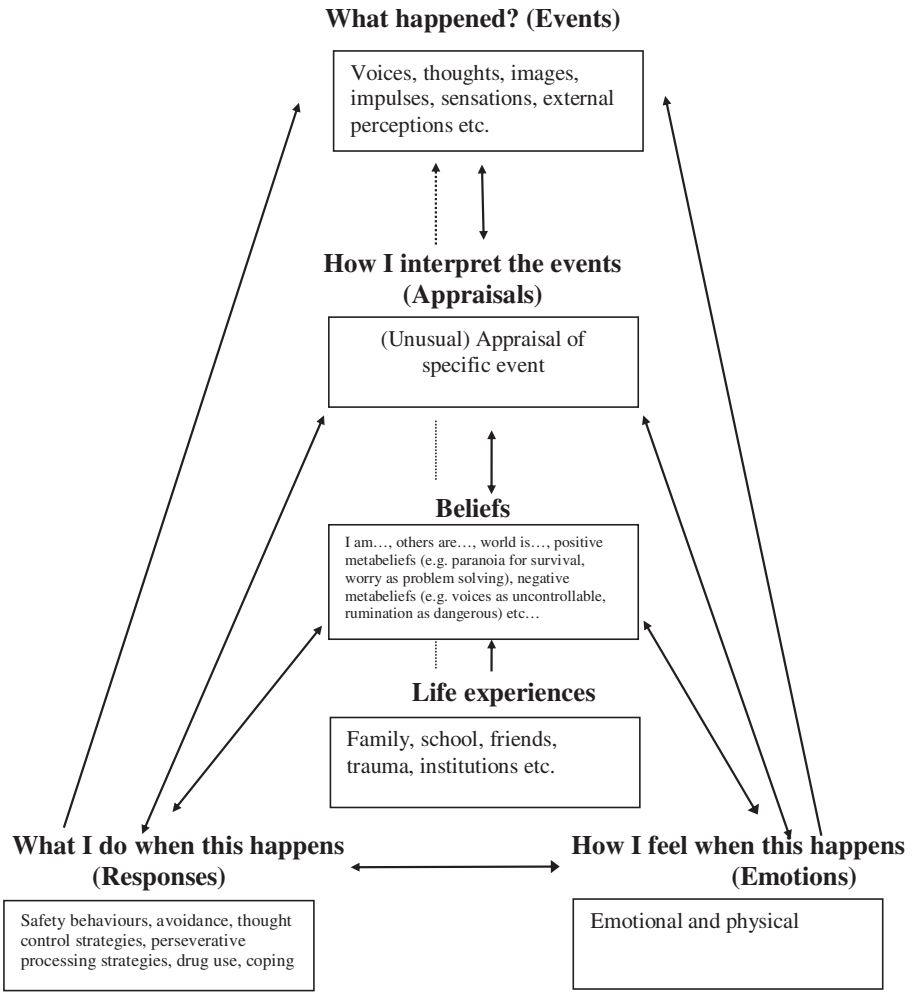

Figure 1. An example of a longitudinal formulation based on the model (with prompts for content).

taking notes or drawing formulations, listening to recording of sessions, in-session behavioural experiments including those in real world settings (e.g. on the bus, in a supermarket).

Between session tasks, for both service user and therapist, are important in ensuring collaborative teamwork towards shared goals and empowering service users through action. The idea that homework enhances therapy should be replaced by the idea that therapy enhances homework.

The *process of thinking*, as well as the content of thoughts, is important. This is achieved by evaluating the helpfulness of how people think as well as what they think, and includes evaluation of metacognitive beliefs and perseverative processing such as worry, rumination and analysing.

An *empirically tested cognitive model* is required in order to derive effective treatments: this is achieved by basing case conceptualisations on the model shown in Figure 1.

Within every session, there should be a review of previous between session tasks (for therapist and service user), a clarification that the goal is still valued, some monitoring of target appraisals of or responses to an experience should occur and a new task to do outside of session is to be agreed for both therapist and participant. A session record is to be completed. Explicit structure (making sure that the format of sessions, agendas, formulations, planning work for between sessions etc. is clear and written) and consistent labels (repeated use of the same terminology once shared and found helpful and acceptable e.g. "What happened", "How I make sense of it" etc. within formulations) will

help service users to learn the process and skills required within sessions and facilitate utilising the approach between sessions.

Between session tasks

Throughout the process of CBTp, there is a strong emphasis on between session tasks for service users and therapists, in order to facilitate change and promote teamwork, active participation and empowerment. An explicit discussion about the importance of such tasks in achieving goals occurs in phase 1. Tasks for service users can be designed to collect information (e.g. diaries or surveys), conduct experiments or practice skills and may also include listening to a recording of the session to facilitate information processing (given memory and attention difficulties), skill learning and eliciting feedback. Tasks for therapists may involve information collection (e.g. conducting a survey on behalf of a service user, reading a book that is relevant to their concerns or information written by service users or writing fact-finding letters on their behalf), arranging a meeting with an independent expert (e.g. a police officer for concerns about safety or a religious community leader for unusual spiritual beliefs, although it is important to talk to these experts first to ensure any information or messages will be helpful to the client), preparing a therapy session summary sheet, carrying out a behavioural experiment or bringing information to sessions (e.g. TED talks or leaflets). It is important to ensure that, at each session, sufficient time (approximately 10–15 min each) is devoted to both reviewing previous tasks and setting new ones. Tasks should be decided upon collaboratively, have a clear rationale, and be meaningful but achievable. Prompts should be established (e.g. SMS reminders) and obstacles considered.

Phases of the protocol

The default milestones and phased structure of this CBTp protocol are outlined below. However, it should be noted there is a need for flexibility and a recognition that not everyone will progress through each phase and that people may move between phases in a non-linear way. Video roleplays illustrating these phases are available at www.psychosisresearch.com/cbt.

(1) Assessment and engagement phase

Within the first session, there is the usual explanation and negotiation of confidentiality, duration, number and frequency of sessions, and an agreement of a short 6–10 session contract with an expectation of renewal up to 30 hours (including booster sessions). There will also be an explanation of CBT, including the above principles. Cognitive behavioural assessment of presenting problems and life experiences and psychosocial history, guided by the cognitive model, will occur (including an element of risk assessment). Normalising information may be provided, if appropriate, and a between session task will be agreed. The delivery of CBTp consistent with the principles and values above aims to be inherently engaging; however, some people may struggle to engage in which case there may be a need to change pace or deviate from the structured protocol.

The default expectation is that, by approximately session 3, there will be a shared list of problems and goals (SMART ones suitable for the agreed short-term contract; goals should ideally be related to increasing quality of life and/or reducing distress; in some instances, telling their story or understanding themselves better can be an appropriate first goal). Identification of a collaboratively prioritised problem list should be followed by goal setting in relation to these. The goals are often not directly related to psychosis, and may be broader recovery goals (e.g. optimism for a better future; understanding self and increasing confidence; improving social networks and relationships; meaningful activity and purpose) or related to other mental health problems that are common in people with psychosis (anxiety, mood, trauma etc.). Priorities are decided according to service user choice, the amenability of the problems to change, and the impact that change in one problem area may have on others. Goals should be reviewed regularly.

There should also be a shared formulation; usually a maintenance formulation of a recent specific situation relevant to the prioritised problems and goals is developed in terms of what happened (event) – how I made sense of it (appraisal) – how I feel (emotion) – what I do (responses). This serves to socialise people with psychosis to the cognitive model (i.e. that it is the interpretation of an event that results in distress and influences the choice of responses made, which may in turn be helpful or unhelpful). Between session tasks will be agreed from the first session onwards and their importance discussed.

(2) Change strategy phase

Once a goal is agreed and there is a maintenance formulation on which to base therapy on, subsequent sessions will include use of change strategies aimed at achieving goals. An agenda is agreed (deciding how to best use time and what to focus on), and will usually include a target related to the current goal and formulation, and review of previous tasks and setting of a new task to do between sessions (for therapist and participant). Specific cognitive, metacognitive and/or behavioural change strategies are selected on the basis of negotiation with the participant (acceptability and what they are willing to try) and formulation (using the formulation to make judgements about the likelihood of success for a given strategy). Given that most sessions last less than an hour, and sufficient time is required for reviewing previous tasks and agreeing new ones, there is an expectation that no more than 2 strategies will occur within a single session. By session 10, the aim is to have had at least one session out in the real world (e.g. a behavioural experiment or observational assessment). These strategies include those listed in other phases as well as here.

Normalisation: this is often done early as it is highly valued by clients and can be a quick way to reduce distress

Examining advantages and disadvantages of events, appraisals and responses (including hearing voices, paranoid or suspicious thoughts, worry, rumination, resisting or engaging with voices): this is often done early as it is important in obtaining informed consent to proceed to use other change strategies. For example, there may be significant advantages to experiences like hearing voices or seeing visions and beliefs such as persecutory or grandiose ideas; if so, the service user should decide if they want to proceed or not, and whether other ways of achieving these positive functions may be required first.

Coping strategies/rational responding/sleep hygiene: this can involve provision of information, use of flash cards, experimenting with different coping strategies, providing safety strategies to allow more challenging work (grounding techniques, relaxation or arousal reduction, subvocalisation for voices).

Role play/skills practice: this can involve role plays of different ways of responding to voices, practicing difficult situations such as social interactions, trying out different ways of responding, video feedback.

Evidential analysis/peripheral questioning: appraisals can be evaluated for accuracy by reviewing current and past evidence. Evidence can also be gathered using diaries. Peripheral questioning refers to a less direct examination, often focusing on consideration of mechanisms and practicalities (such as how many people may be required to keep someone under surveillance, how much they would be paid, how much the equipment would cost etc.).

Generating alternative explanations: this involves generating alternative explanations for what happened (event), in addition to the original problematic appraisal, and considering the emotional consequences of each alternative appraisal. These can also be included in a pie chart to help re-evaluate the original appraisal, which would be the last one entered into the pie.

Survey planning/review: Surveys can be useful to gain alternative perspectives or to gather evidence regarding a particular belief. They can also normalise certain experiences, thoughts or responses (e.g. by asking others if they have experienced anything similar, what it would mean to experience such a thing, whether they would judge people negatively etc.), and to generate ideas for coping or alternative responses based on other people's experiences and opinions. Surveys can be designed in session and conducted between sessions (by therapists and/or service users) and the results examined in a subsequent session. It is important to have an open-ended feedback box to allow participants to provide qualitative feedback in addition to answering the specific questions.

Beliefs/expectations about success and pleasure: Beliefs about the likelihood of success and/or pleasure related to tasks appears to be implicated in difficulties such as anhedonia and avolition. Exploring and evaluating these beliefs in conjunction with graded task assignments can be helpful.

Reducing social isolation/graded activity scheduling/mastery and pleasure/schedule success: Carefully targeted activity scheduling, increasing social contacts and widening social networks can all be used to directly achieve behavioural goals in addition to testing out beliefs and expectations about success and pleasure.

Safety-seeking behaviours/behavioural experiments in-session/therapist-assisted/ exposure: Behavioural experiments offer a framework for going out into the world to test out concerns and discover new information. They must be collaboratively designed with regard to deciding the prediction to test out, defining the predicted outcome in observable and measurable terms, and identifying any safety-seeking behaviours to be reversed for true exposure to test the belief. The results should be summarised and understood with reference to the formulation. The most challenging behavioural experiments (e.g. abandoning safety-seeking behaviours to test persecutory ideas) are often in later stages of therapy, whereas less risky, no-lose experiments often occur early (e.g. evaluating the usefulness of thought suppression; testing thought broadcast using a digital recorder). Most behavioural experiments will be conducted in the presence of the therapist.

Modifying environment: If upon evaluating situational analyses it becomes apparent there that appraisals are accurate, then action plans can be used to solve the problems that have been identified. This may involve problem solving, identifying others who may be able to offer assistance (including police and social services), using role play to rehearse strategies and modifying the physical environment.

Metacognitive beliefs (e.g. positive/negative beliefs about paranoia/rumination/worry): Evaluating the origins of and current evidence for positive and negative beliefs about mental processes including paranoid thoughts, worry, rumination and analysing situations can be useful.

Metacognitive strategies (e.g. postponing perseverative processing; detached mindfulness): If extended perseverative processing is considered to be unhelpful, then strategies such as postponing worry or rumination until a later time (at which point the person can choose to engage in this form of thinking or not) can be helpful in achieving goals. If people struggle to disengage, experiential exercises and the practice of detached mindfulness (allowing thoughts to come and go without engaging with them in an effortful way) can facilitate this choice.

Attentional strategies (e.g. external focus, attention training): Manipulation of attentional focus can be helpful in increasing choice and flexibility regarding attentional control and reducing self-consciousness is often useful.

(3) Longitudinal formulation phase

The timing of this phase, which involves collaborative development of a shared historical formulation based on the specific cognitive model (see Figure 1 for a template with prompts for therapists regarding content), can vary considerably. A historical formulation incorporating life experiences and beliefs formed as a result can be helpful in many ways including demonstrating listening and understanding, validation of experience, creating optimism for change and identifying specific change strategies most likely to succeed in goal attainment. It often occurs around the mid-point of therapy, but may not occur until the end of therapy (for consolidating gains and avoiding recurrence of problems) or not at all. Reasons for progressing to this phase include: linking problems together after multiple maintenance formulations or in order to make multiple problems that feel overwhelming seem related and linked into one; needing a third possible explanation for their experiences if they feel caught between mental illness or unusual, distressing appraisals (e.g. either I'm schizophrenic or I'm being possessed by demons); feeling stuck when working at the maintenance level; to help prevent relapse by understanding initial problem development. It may also be done earlier in therapy; for example, if the person recounts their life story in the first session and is already making links between early traumatic experiences and current

problems, or if the prioritised goal is understanding their difficulties ("Why me?"). It is also important to emphasise that generating a longitudinal formulation is not compulsory, and should be offered as a choice. When producing such formulations, it is important to relate it to the goals (usually feeling better or changing "what I do" to improve quality of life), and it should be drawn from scratch, rather than using a template. There should be a good match between appraisal and emotion, and emotion and behaviour and the arrows, which can be used to plan treatment, should only be drawn in with agreement (otherwise collaboratively investigate the hypothesised relationships).

Finally, consent should be obtained and exacerbations prepared for, since examining historical difficulties can be distressing; monitoring emotional response during and getting feedback at the end of sessions is important. In this stage it is more likely that change strategies will include belief restructuring, more challenging behavioural experiments and imagery modification:

Imagery modification: imagery modification techniques can be used to help modify distressing content or to increase the person's sense of control over the images. Most people with psychosis experience recurrent, distressing images (e.g. regarding agents of voices, voice content, paranoid catastrophes, trauma-related flashbacks, stigmatising self-image). These are often more emotive than verbal thought, so techniques including treating the image as a video, introducing a rescuer or an alternative outcome to the image and introducing humour can all be effective.

Core beliefs/schema change/self-prejudice metaphor: Schema change methods for working with long-standing, strongly held beliefs about self, world and others can be helpful when working with people experiencing psychosis, especially considering the incidence of difficult early life experiences that are commonly associated with psychosis. Strategies include the predjudice metaphor (Padesky, 1993) to show how negative self-beliefs can act as self-prejudice via which contradictory information is dismissed and confirmatory information is processed. Advantages and disadvantages analyses of core beliefs, rules or assumptions are advised, including examination of short-term versus long term utility of these beliefs, particularly as these beliefs may have developed as an adaptation to difficult early life experiences. Other techniques include the historical test of a belief, continuum methods, pie charts for responsibility and guilt and positive data logs (Padesky, 1994).

(4) Consolidation phase

Relapse prevention/blueprint/monitoring and action plans: The aim of the final few sessions (often between 2 to 4) is to develop a therapy blueprint for the maintenance of gains and relapse prevention. The therapy blueprint can include information on the goals of therapy, the outcome of therapy in terms of progress towards these goals, a copy of the formulation, a summary of useful strategies, and a collaborative plan for action for the maintenance of gains. It can vary in format (e.g. written information, audio or video recordings, pictorial information) and length according to client preference. It should be developed collaboratively with the client leading decisions about purpose, format and content.

Booster sessions may also be offered in order to facilitate consolidation of knowledge and skills and provide a safety net.

Implementation issues and challenges

Much of the therapy delivered in the trials is conducted in the person's home. This reduces non-attendance and is consistent with assertive outreach principles, but can create practical challenges (e.g. use of carbon paper to cope with no access to a photocopier; conducting sessions while walking in a park to cope with no available private space at home). Text messages and phone calls to remind service users of appointments are important. Ideally, the trial participants have care coordinators who are responsible for management of risk and practical issues such as housing, finances and family relationships. However, there are many occasions when trial therapists have to take responsibility for such issues, which can make linear progression towards therapeutic goals difficult. On the other hand,

writing letters of support for housing, college places and support with daily activities, or accompanying someone to a related appointment can be helpful for engagement purposes, may increase the likelihood of a successful outcome and can provide a useful opportunity for observational assessment and behavioural experiments. Similarly, liaison with other health professionals, family members, teachers and residential care staff can be time-consuming, but is often important for both engagement of the service user and ensuring CBTp is likely to be most effective and sustainable.

Other challenges include difficulties with forming a relationship, establishing trust or motivation to change; this may result in a slower pace, extended work establishing goals, discussion of previous and current interests (to identify goals), discussion of the relationship and using a longitudinal formulation.

Memory and attentional difficulties obviously can limit progress, so identifying strategies, prompts and co-workers to overcome these are required. The complex, systematised belief systems can also present a challenge, since therapist and therapy can easily be incorporated within this; it is important to check out whether service users consider therapists to be involved, and such belief systems are often more responsive to behavioural or metacognitive approaches rather than evidential analysis, alternative explanations and other verbal reattribution methods that address content of thinking. Finally, although CBTp involves hard work and commitment from the service user and therapist alike, it is important to try to make the process as enjoyable as possible, with use of humour and curious exploration where appropriate. The use of a standardised protocol should not prohibit creativity and spontaneity within therapy or therapist, but help to ensure that these factors utilised effectively if a protocol is used flexibly as opposed to rigidly.

While adherence to a manualised protocol should increase the likelihood, on average, of achieving positive results, it is clear that CBTp is not a panacea and is not going to be helpful or acceptable to all. The qualitative studies, in particular, suggest that even those who have benefitted recognise that there would have been times when it would not have suited them. Unfortunately, the evidence base is not yet able to address the questions of when and for whom CBTp is most appropriate (and the same is true for pharmacological approaches); therefore, the current guidance recommending it be *offered* to all seems reasonable (and replicates the approach of informed consent within the trials). It is also important that CBTp continue to develop and increase effectiveness, since it has been fairly criticised on the basis that, for example, the effect sizes are only small to moderate (Thomas, 2015) and that the conceptual models on which it is based may not accurately capture the phenomenological characteristics of all psychotic experiences (Škodlar, Henriksen, Sass, Nelson, & Parnas, 2013). However, until the evidence base for alternative psychosocial approaches (e.g. ACT, CFT, mindfulness or psychodynamic approaches) is stronger, following the recommendation to offer CBTp as first line for people with psychosis is consistent with good clinical practice. If people do not engage with or respond to CBTp then alternative psychosocial approaches should be considered. Similarly, if people with psychosis make truly informed choices to try an alternative (based on descriptions of therapeutic approaches and the available evidence, or in a research trial context), then this also seems appropriate.

Conclusion

The use of a protocol for CBTp that has been evaluated in clinical trials, is based on a specific, empirically-tested cognitive model and adheres to the principles and values of CBTp as well as a phased approach to assessment, formulation and change strategies, should help to maximise the likelihood of replicating results obtained within the trials. The emphasis on collaboration and teamwork, active participation on the part of service users and regular feedback, reviewing of goals and a normalising philosophy should increase the chance of benefits and decrease the likelihood of any unintended harms. Use of session records, fidelity and competence ratings and recording-based supervision should also be helpful in this respect. Future research trials can answer specific research questions regarding the importance of particular principles, components and phases. Clinical services could evaluate the impact of adhering to protocols and investigate the usefulness of session records, supervision structures and competency ratings in achieving good outcomes in routine practice.

Acknowledgements

This protocol has evolved over two decades with input from trial supervisors (including Paul French, Samantha Bowe, Paul Hutton), trial therapists (including Julia Renton, Steve Williams, Hazel Dunn, Sophie Parker, Vicky Brooks, Nicola Chapman, Liz Murphy, Lisa Wood, Natasha Holden, Rachel MacLeod, Jane Hutton, Ann Steele, Jasper Palmier-Claus), principal investigators at other sites (including Max Birchwood, Alison Brabban, Rob Dudley, David Fowler, Andrew Gumley, David Kingdon, Matthias Schwannauer, Douglas Turkington), user-researchers (Rory Byrne, Martina Kilbride, Eleanor Longden, Liz Pitt), participants from our trials (via qualitative interviews) and service user consultants (our Service User Reference Group).

Disclosure statement

APM delivers training workshops and has written textbooks on the topic of CBT for psychosis, for which he receives fees/royalties. He also conducts funded research on CBT for psychosis and delivers CBT in the NHS.

References

Blackburn, I. M., James, I., Milne, D., Baker, C. A., Standart, S., Garland, A., & Reichelt, F. K. (2001). The revised cognitive therapy scale (CTS-R): Psychometric properties. *Behavioural and Cognitive Psychotherapy, 29*, 431–446.

Brabban, A., Byrne, R., Longden, E., & Morrison, A. P. (2016). The importance of human relationships, ethics and recovery-orientated values in the delivery of CBT for people with psychosis. *Psychosis: Psychological, social and integrative approaches*. doi: 10.1080/17522439.2016.1259648

Clark, D. M. (1986). A cognitive approach to panic. *Behaviour Research and Therapy, 24*, 461–470.

Clark, D. M., & Wells, A. (1995). A cognitive model of social phobia. In: R. G. Heimberg & M. R. Liebowitz (Eds.), *Social phobia: Diagnosis, assessment, and treatment* (pp. 69–93). New York, NY: Guilford Press.

Dunn, G., Fowler, D., Rollinson, R., Freeman, D., Kuipers, E., Smith, B., & Steel, C. (2012). Effective elements of cognitive behaviour therapy for psychosis: results of a novel type of subgroup analysis based on principal stratification. *Psychological Medicine, 42*(5), 1057–1068. doi:10.1017/S0033291711001954

Ehlers, A., & Clark, D. M. (2000). A cognitive model of posttraumatic stress disorder. *Behaviour Research and Therapy, 38*, 319–345.

Flach, C., French, P., Dunn, G., Fowler, D., Gumley, A. I., Birchwood, M., … Morrison, A.P. (2015). Components of therapy as mechanisms of change in cognitive therapy for people at risk of psychosis: analysis of the EDIE-2 trial. *The British Journal of Psychiatry, 207*(2), 123–129. doi:10.1192/bjp.bp.114.153320

Fowler, D., Garety, P., & Kuipers, E. (1995). *Cognitive-behaviour therapy for psychosis: theory and practice*. Chichester: Wiley.

French, P., & Morrison, A. P. (2004). *Early detection and cognitive therapy for people at high risk of developing psychosis*. London: Wiley.

van der Gaag, M., Valmaggia, L. R., & Smit, F. (2014). The effects of individually tailored formulation-based cognitive behavioural therapy in auditory hallucinations and delusions: A meta-analysis. *Schizophrenia Research, 156*(1), 30–37. doi:10.1016/j.schres.2014.03.016

Jauhar, S., McKenna, P. J., Radua, J., Fung, E., Salvador, R., & Laws, K. R. (2014). Cognitive-behavioural therapy for the symptoms of schizophrenia: systematic review and meta-analysis with examination of potential bias. *The British Journal of Psychiatry, 204*(1), 20–29. doi:10.1192/bjp.bp.112.116285

Kilbride, M., Byrne, R., Price, J., Wood, L., Barratt, S., Welford, M., & Morrison, A. P. (2013). Exploring service users' perceptions of Cognitive Behavioural Therapy for psychosis: A user led study. *Behavioural and Cognitive Psychotherapy*, *41*, 89–102. doi:10.1017/S1352465812000495

Kingdon, D., & Turkington, D. (2005). *Cognitive therapy for schizophrenia*. New York, NY: Guilford Press.

Morrison, A. P. (2001). The interpretation of intrusions in psychosis: An integrative cognitive approach to hallucinations and delusions. *Behavioural and Cognitive Psychotherapy, 29*, 257–276.

Morrison, A. P., & Barratt, S. (2010). What are the components of CBT for Psychosis? A Delphi study. *Schizophrenia Bulletin, 36*, 136–142.

Morrison, A. P., French, P., Stewart, S., Birchwood, M., Fowler, D., Gumley, A. I., … Dunn, G. (2012). Early detection and intervention evaluation for people at risk of psychosis: Multisite randomised controlled trial. *BMJ, 344*, e2233.

Morrison, A. P., French, P., Walford, L., Lewis, S. W., Kilcommons, A., Green, J., & Bentall, R. P. (2004a). Cognitive therapy for the prevention of psychosis in people at ultra-high risk: Randomised controlled trial. *The British Journal of Psychiatry, 185*, 291–297.

Morrison, A. P., Renton, J. C., Dunn, H., Williams, S., & Bentall, R. P. (2003). *Cognitive therapy for psychosis: a formulation-based approach*. London: Psychology Press.

Morrison, A. P., Renton, J. C., French, P., & Bentall, R. P. (2008). *Think you're crazy? Think again: A resource book for cognitive therapy for psychosis*. London: Routledge.

Morrison, A. P., Renton, J. C., Williams, S., Dunn, H., Knight, A., Kreutz, M., … Dunn, G. (2004b). Delivering cognitive therapy to people with psychosis in a community mental health setting: An effectiveness study. *Acta Psychiatrica Scandinavica, 110*, 36–44.

Morrison, A. P., Turkington, D., Pyle, M., Spencer, H., Brabban, A., Dunn, G., & Hutton, P. (2014). Cognitive therapy for people with schizophrenia spectrum disorders not taking antipsychotic drugs: A single-blind randomised controlled trial. *The Lancet, 383*. doi:10.1016/S0140-6736(13)62246-1

National Institute for Clinical Excellence (2013). *Psychosis and schizophrenia in children and young people: Recognition and management*. London: NICE.

National Institute for Health and Care Excellence (2014). *Psychosis and schizophrenia in adults: treatment and management*. London: NICE.

Padesky, C. A. (1993). Schema as self-prejudice. *International cognitive therapy newsletter, 5*, 16–17.

Padesky, C. A. (1994). Schema change processes in cognitive therapy. *Clinical Psychology and Psychotherapy, 1*, 267–278.

Pyle, M., Norrie, J., Schwannauer, M., Kingdon, D., Gumley, A., Turkington, D., & Morrison, A. P. (2016). Design and protocol for the Focusing on Clozapine Unresponsive Symptoms (FOCUS) trial: a randomised controlled trial. *BMC Psychiatry, 16*(1), 1–12. doi:10.1186/s12888-016-0983-6

Roth, A. D., & Pilling, S. (2013). *A competence framework for psychological interventions with people with psychosis and bipolar disorder*. London: University College London.

Škodlar, B., Henriksen, M. G., Sass, L. A., Nelson, B., & Parnas, J. (2013). Cognitive-behavioral therapy for schizophrenia: A critical evaluation of its theoretical framework from a clinical-phenomenological perspective. *Psychopathology, 46*, 249–265.

Stafford, M. R., Jackson, H., Mayo-Wilson, E., Morrison, A. P., & Kendall, T. (2013). Early interventions to prevent psychosis: systematic review and meta-analysis. *BMJ, 346*, f185. doi:10.1136/bmj.f185

Thomas, N. (2015). What's really wrong with cognitive behavioral therapy for psychosis? [Opinion]. *Frontiers in Psychology, 6*, doi:10.3389/fpsyg.2015.00323

Wells, A. (1995). Meta-cognition and worry: A cognitive model of generalized anxiety disorder. *Behavioural and Cognitive Psychotherapy, 23*, 301–320.