

BRIEFING PAPER

DEVELOPMENT OF A RANDOMISED CONTROLLED TRIAL OF COUNSELLING FOR DEPRESSION

DRAFTED BY: MICK COOPER, PROFESSOR OF COUNSELLING, UNIVERSITY OF STRATHCLYDE
CORRESPONDENCE TO: ANDY HILL, HEAD OF RESEARCH, BACP, ANDY.HILL@BACP.CO.UK

SUMMARY

Many members of the UK counselling community feel that their profession and practice is under threat, particularly within NHS settings. This can be attributed, primarily, to the near-complete absence of recommendations for counselling in clinical guidelines, as a consequence of the relative lack of randomised controlled trial (RCT) evidence in support of this therapy. Expert opinion suggests that this need for RCT evidence is likely to continue for the foreseeable future.

In recent years, BACP has led the development of Counselling for Depression (CfD), a systematic, person-centred experiential treatment for depression, based on evidenced humanistic competences. The development of this intervention and its roll out into some Improving Access to Psychological Therapies (IAPT) services gives the counselling community one of its best opportunities, yet, to develop a body of RCT evidence in support of counselling. Expert opinion leans towards two specific strategies for trialling CfD: first, a relatively short-term comparison of CfD against waiting list in IAPT settings; second, a more extended trial comparing the effectiveness of CfD against CBT.

It is recommended that BACP set up a CfD RCT Task Force to take forward these projects, possibly through the development of pilot trials; and to look at ways of developing a more RCT-friendly culture within the counselling community.

AIMS

To brief the British Association for Counselling and Psychotherapy (BACP) on the development of a randomised controlled trial (RCT) of Counselling for Depression (CfD).

METHOD

Interviews (phone, Skype or face-to-face) were conducted with 25 key figures in the psychological therapies research, policy and commissioning field. Relevant practitioner and academic networks were also contacted and key documents in the field were reviewed.

BACKGROUND

Representatives of counselling and person-centred organisations indicate that many of their members feel that their profession and orientation is under threat, with counselling services being decommissioned in NHS settings. This is mainly attributed to the emergence of the Improving Access to Psychological Therapies programme (IAPT), and to clinical guidelines (National Institute for Health and Clinical Excellence [NICE] and Scottish Intercollegiate Guidelines Network [SIGN]) in which there are minimal, or no, recommendations for counselling or counsellor-based therapies.

Depression

'Depression is the most common mental disorder in community settings' [1], and is a principal focus for psychological interventions in the NHS. NICE guidelines [1], drawing from the DSM-IV, use the following levels of depression: 'subthreshold depressive symptoms', 'mild depression', 'moderate depression', and 'severe depression'.

Current clinical guidelines for counselling

NICE Guidelines on the treatment and management of depression in adults [1]
NICE Guidelines recommend a range of psychological interventions for depression, including CBT, interpersonal therapy (IPT), behavioural activation (BA) and behavioural couples therapy. With respect to counselling, NICE Guidelines [1] currently state:

- '8.11.3.4 For people with depression who decline an antidepressant, CBT, IPT, behavioural activation and behavioural couples therapy, consider:
- counselling for people with persistent subthreshold depressive symptoms or mild to moderate depression'

And add:

'Discuss with the person the uncertainty of the effectiveness of counselling...in treating depression.'

The NICE Guidelines [1] also include the following research recommendation:

- '8.12.1.4 The efficacy of counselling compared with low-intensity cognitive behavioural interventions and treatment as usual in the treatment of persistent subthreshold depressive symptoms and mild depression.'

The last update of these guidelines was in 2010, and another update is not expected for 'quite a few years.' However, if new evidence becomes available, they may be partially updated.

NICE: Depression with a chronic physical health problem [2]

Counselling is not recommended in the NICE guidelines for treatment of depression with a chronic physical health problem. However, the following research recommendation is made:

- 7.5.4 The efficacy of counselling compared with low-intensity cognitive and behavioural interventions and treatment as usual in the treatment of depression in patients with a chronic physical health problem [2].

SIGN National Clinical Guidelines on Non-pharmaceutical management of depression in adults [3]

With respect to counselling, SIGN guidelines state that 'There is insufficient consistent evidence on which to base a recommendation.'

'*The Matrix*' [4]

'The Matrix is a guide to planning and delivering evidence-based Psychological Therapies within NHS Boards in Scotland' [4]. Consistent with SIGN guidelines, there is no recommendation for counselling in the treatment of depression.

The empirical status of counselling

The minimal presence of counselling in clinical guidelines can be primarily understood in terms of two factors: 1. The prioritising of RCT evidence in clinical guidelines; 2. The relative lack of RCT evidence for counselling with depression.

Emphasis on RCT evidence

Currently, all SIGN, NICE and Matrix recommendations for specific psychological interventions for the treatment of depression are based on RCT evidence [1-4]. This is relatively consistent with the approach adopted by developers of clinical guidelines in other countries, such as the American Psychological Association's Division 12 Society of Clinical Psychology list of effective psychological treatments (<http://www.div12.org/PsychologicalTreatments/treatments.html>); and the list of psychological interventions that will be funded by German health insurance (Gemeinsamer Bundesausschuss Ärzte und Krankenkassen, <http://www.g-ba.de/>).

While NICE *does* draw on case study, qualitative and client experience research to make recommendations on the way psychological therapies should be delivered, these non-RCT forms of evidence are not used to inform the *specific* therapeutic orientations recommended. NICE depression guidelines state: 'In healthcare research the RCT is considered the gold standard for establishing a treatment's efficacy due to its ability to distinguish, in an unbiased manner, between treatment outcomes and outcomes for the group who did not receive treatment' [1].

RCT evidence for counselling

In contrast to NICE-recommended therapeutic interventions such as CBT, only a small number of RCTs of counselling for depression exist [for a review of this research, see 5], and their findings are described as 'inconclusive' [e.g., 6]. Counselling-related RCTs tend to have comparatively low numbers [e.g., 7], meaning low power to detect significant findings; and there is also a lack of consistency in the particular intervention being delivered.

A Health Technology Assessment (HTA) funded trial, led by Michael King, of counselling compared with CBT and usual GP care 'in the management of depression as well as mixed anxiety and depression in primary care' [8] is considered by many in the field the strongest evidence for the effectiveness of counselling, demonstrating its superiority over GP usual care at four months (but not 12 months) and no significant differences against CBT. However, evidence from this trial has now been excluded from both NICE and SIGN guidelines because not all participants in the trial had a diagnosis of major depression, some being diagnosed with mixed anxiety and depression or other anxiety states. (Note, a re-analysis of data from the CBT and counselling arms of this trial has now been conducted, and submitted for publication, using only clients with an ICD10 primary or secondary diagnosis of major depression).

The exclusion of such evidence led some informants to feel that guideline development committees were 'stacked' against counselling and humanistic therapies; and that it was not enough to produce RCT evidence, as people were needed on the committees to interpret and support these forms of practice.

Counselling for Depression (CfD)

In 2007, with the establishment of the IAPT programme, Professors Anthony Roth and Stephen Pilling at University College London were commissioned to develop a set of competences for the delivery of CBT for adults with common mental health problems. Competences were drawn from manuals of cognitive-behavioural interventions that were of proven effectiveness in randomised controlled trials. In 2008 and 2009, this process was extended to the development of competences in three other therapeutic orientations, including person-centred and experiential (subsequently termed 'humanistic') psychological therapies [9]. The Expert Reference Group for the development of these humanistic competences including two representatives of the BACP: Sally Aldridge and Nancy Rowland; Janet Tolan, a representative of the British Association for the Person-Centred Approach (BAPCA), and two UK-based professors of counselling: Robert Elliott and Mick Cooper. Andrew Hill, then Senior Lecturer in Counselling at the University of Salford (subsequently Head of Research at the BACP), was commissioned to draft the competences, in association with Roth and Pilling.

Subsequently, a team from the BACP, led by Andrew Hill, was commissioned by the IAPT programme to develop a set of competences for 'Counselling for Depression' (CfD) [10], derived from Roth, Hill and Pilling's [9] humanistic psychological therapies competences. These CfD competences primarily drew from the person-centred and emotion-focused elements of the broader humanistic framework, with a particular orientation towards the treatment of depression across the full spectrum of severity. Training for IAPT counsellors in CfD competences

began in 2010, with an expectation that around 90 counsellors would initially be trained in this intervention, to then be delivered across a variety of IAPT sites. For people with persistent subthreshold depressive symptoms or mild to moderate depression, 6 - 10 sessions of CfD are recommended; while up to 20 sessions are recommended for people with more severe cases of depression.

The background to the development of CfD means that, in the present context, the term 'counselling' is used to refer to a primarily person-centred form of psychological therapy. This is consistent with its usage in most medical contexts [e.g., 1-2, 3], although it is recognised that, in the UK counselling field itself, the term can be inclusive of a wide range of psychological practices, including 'CBT counselling' and 'psychodynamic counselling.'

BACP informants emphasised that the use of the term 'counselling' in this way was purely pragmatic, and in no way an attempt to appropriate the term for person-centred therapy alone. It was also acknowledged that, in the future, it may be important to move towards use of the full modality title for this intervention: 'person-centred experiential counselling for depression'. However, BACP informants also stated that around 70% of BACP members had trained in a person-centred or humanistic orientation; and that person-centred therapy was particularly vulnerable to 'dropping off the end' of the NHS radar, as there were no strong research groups taking RCTs of this approach forward (in contrast, for instance, to the work of Peter Fonagy, Alessandra Lemma-Wright and colleagues in the development of Dynamic Interpersonal Therapy [DIT]). Hence, BACP informants felt that the present, specific focus on supporting person-centred counselling was justified.

THE IMPORTANCE OF RCT EVIDENCE IN THE SHORT AND MEDIUM TERM FUTURE FOR THE RECOMMENDATION AND COMMISSIONING OF PSYCHOLOGICAL THERAPIES

Several informants indicated that they had 'heard noises', or 'lip-service' paid, to non-RCT methods. However, *all* informants stated that they did not believe that the current emphasis on RCT evidence would lessen. Rather, they believed that RCTs were 'here to stay,' and that evidence from such studies would continue to play a decisive role in determining which psychological interventions were recommended and commissioned within the NHS for the foreseeable future. This view was shared by both advocates, and critics, of RCT methodologies; service providers and representatives of service user organisations; and was consistent with views on wider developments in Europe and the USA.

This viewpoint comprised of two components. First, it was argued that NHS commissioning would continue to be strongly influenced by clinical guidelines from NICE/SIGN. One informant stated that it was 'inconceivable' that the government would change their view on NICE as the driving force in decision-making on what treatments should be made available in NHS England. It was argued that this was because NICE was seen as an impartial, independent body. Two informants pointed to the recent government white paper, *Liberating the NHS* [11], as evidence that NICE would continue to act as the 'arbiter of treatments'. One informant stated that clinical guidelines were essential for clear decision making. The existence of

treatment guidelines was supported by user representatives. It was argued that the large government investment in IAPT would not have taken place without the existence of NICE guidelines.

Second, it was argued that NICE and SIGN would continue to prioritise evidence from randomised controlled trials within the field of psychological therapies. While non-RCT evidence may inform clinical guidelines in fields in which it is not possible or ethical to conduct RCT research (for instance, emergency services), it was emphasised that the psychological therapies is not one of these fields. A large body of RCT evidence exists, and is being amassed on an ongoing basis. Therefore, there was little reason for psychological therapies guidelines groups to turn to non-RCT evidence. Several informants also stated that, as medically-based and -informed institutions, NICE and SIGN were inevitably going to prioritise on medically-oriented methodologies.

THE IMPORTANCE OF NON-RCT EVIDENCE IN THE SHORT AND MEDIUM TERM FUTURE

Nearly all informants did believe that, in the coming years, there would be moves towards a broadening of the kinds of evidence that would be used to inform clinical guidelines -- both in the UK and in Europe. However, most of these informants felt that this non-RCT evidence would act as *supplementary*, and not as an alternative, to RCT evidence -- insufficient, in itself, to form the basis for clinical recommendations. RCT evidence, therefore, would continue to be considered essential in establishing the effectiveness of an intervention: the 'bottom line.'

Cohort studies

'Cohort studies' (which look at changes in groups of clients over time), a form of 'practice-based evidence' (PBE), were mentioned by several of the informants as an important, non-RCT form of evidence that could begin to inform clinical guidelines, indicating the generalisability of evidence-based treatments to actual populations and acting as a 'quality assurance' mechanism.

Some informants believed that, at some point, cohort studies might serve for the basis of clinical recommendations in themselves -- particularly with the development of electronic technologies which allowed for the accumulation of 'huge' practice-based datasets at relatively minimal costs. There was also the collection of a substantial body of PBE within IAPT itself. It was argued, however, that the methodology for such studies would need to be of the highest possible standard to influence clinical guidelines: for instance, formal diagnosis, blind assessment, adequate follow-up, evidence of treatment fidelity (i.e., clients actually receiving the treatment they are supposed to), recording of random sessions for auditing, and complete and accurate data on all clients. Other informants, however, believed that the number of confounds in such studies meant they could never, in themselves, act as the basis for clinical recommendations; and would always act as a 'poor relation' to RCTs.

Patient experience studies

The importance of 'patient experience' studies was emphasised by one informant: qualitative or quantitative research that looked at clients' particular experiences of care. It was highlighted that such research was an essential complement to randomised controlled designs, as a treatment may be effective but so unpleasant that it would not be appropriate to recommend. Such evidence is now included in NICE guidelines for depression [1] and for depression in adults with a chronic health problem [2], though it does not inform which specific treatments are recommended.

Treatment safety research

Research into the safety of treatments was also highlighted as essential for influencing clinical guidelines.

Client preferences

Client preference studies (in which clients are given a preferred, rather than randomly selected, treatment) were noted by one informant as an emerging source of potentially influential data; as well as studies of clients' preferences for treatments, per se.

Mechanisms of change research

One informant felt that there would be a move towards studies which identified mechanisms of change, for instance through the use of magnetic resonance imaging (MRI) of psychotherapy clients.

RCT EVIDENCE FOR COUNSELLING IN DEVELOPMENT

Informants were not aware of any RCTs currently in progress, either in the UK, Europe or the US, that were specifically intended to evaluate the effectiveness of counselling or person-centred experiential therapy for depression.

However, a current trial, developed by Dr Hugh McPherson at the University of York to evaluate the effectiveness of acupuncture for individuals diagnosed with depression or mood disorder (ACUDep, see <http://isrctn.org/ISRCTN63787732>), does contain a counselling arm with an intended recruitment of 292 participants, as well as a Usual GP Care arm of an intended 146 participants. Counselling being delivered is manualised and based on the Skills for Health humanistic competences [9], with involvement of a BACP colleague on the Study Steering Group. Although the counselling being delivered does not specifically follow the Counselling for Depression manual and there is no external auditing of fidelity to counselling competences, the results from this trial, due around 2013, should make a useful contribution to the body of evidence of the effectiveness and cost-effectiveness of counselling.

In addition, Dr Beth Freire, at the University of Strathclyde, is currently working with colleagues at Strathclyde and Glasgow Universities to develop a proposal for a trial comparing counselling, low intensity CBT, and treatment as usual

for the treatment of persistent subthreshold depressive symptoms and mild depression (CLICD pilot), as per NICE research recommendations.

In 2011, it is expected that Cochrane reviews will be published of humanistic therapies versus treatment as usual for depression [12], and humanistic therapies versus other psychological therapies for depression [13]. In addition, it is expected that the Cochrane Review of the effectiveness and cost-effectiveness of counselling in primary care will be updated [14].

As indicated above, re-analyses of data from previous trials of counselling for depression may be published, specifically tailored to meet NICE and SIGN requirements.

RECENT SUBMITTED PROPOSALS

In July 2009, a team of highly experienced researchers led by Professor Michael King of UCL/Priment Clinical Trials Unit, and including colleagues at the BACP (Nancy Rowland) and representatives of the CBT and clinical psychology field (Professors Tony Roth and Stephen Pilling), submitted a funding proposal for a 'non-inferiority, randomised controlled trial of the clinical and cost effectiveness of person-centred Counselling versus Cognitive behaviour therapy for patients with major depression in general practice' (ON THE COUCH trial) to the NIHR Health Technology Assessment programme's Clinical Evaluation and Trials workstream. The study was proposed to take place in primary care settings in England that were involved in the IAPT programme; with 488 participants diagnosed with DSM-IV major depression randomly assigned up to 20 sessions of either CBT or person-centred counselling, the latter based on the Roth, Hill and Pilling competences for humanistic psychological therapies [9]. The proposal was rejected prior to shortlisting by the HTA Clinical Evaluation and Trials Prioritisation Group, which advises the Programme on the importance of the specific research question to the NHS. The rejection letter states: 'The Group felt that the case for the importance of this research question to the NHS was not as strong as for other proposals under consideration.' Unfortunately, no further individual feedback was available, with no further correspondence possible on the application.

DEVELOPING AN RCT OF COUNSELLING FOR DEPRESSION

All informants were asked how they might go out about developing and designing an RCT of CfD.

Basic requirements

All informants stated that any trial would need to meet the highest standards of trial design, ethics and reporting (see, for instance, <http://www.consort-statement.org/>) including such elements as concealed randomisation, blinding of assessors and exclusion of clients exhibiting suicidality). Other basic design elements that informants believed would be essential to such a trial were:

- A qualitative, 'experience of care' assessment built in to the trial: to consider such aspects of the treatment(s) as comfort, choice, provision of information, involvement of family and carers and applicability to healthcare in general (see, for example, <http://www.pickereurope.org/>).
- Use of a clearly-defined and structured manual; specifying, for instance, how the CfD is done, how it unfolds over time (i.e., above and beyond simply listing competences), and number of sessions.
- Clear programme, and statement, of therapists' training and supervision; with adequate checks of competence and fidelity to CfD.
- Monitoring, and reporting, of medication intake of participants in trial.
- Economic analysis.
- User involvement in the design of the study.
- The use of measures that reflect the aims and orientation of counselling -- such as strength- and wellbeing-based measures and personalised goal inventories -- as well as more diagnostic-based indicators.
- Analysis of mediators of change (e.g., dysfunctional thinking, therapeutic alliance) to identify change processes as well as outcomes.
- In-depth qualitative interviews to identify mechanisms of change, helpful and unhelpful processes.
- An openness amongst the research team to 'negative' findings (i.e., evidence that counselling was not effective), and a willingness to learn from such outcomes.

In addition, one informant stated that s/he thought it was essential, prior to any decisions about design, to consult with colleagues at NICE/SIGN to assess whether any proposed design would be 'taken seriously' by these guidelines development groups.

Pilot study

Several members of the BACP Research committee felt that, prior to any full trial, an 18 month pilot study should be conducted to identify -- and address -- any practical difficulties that might emerge in such a study; to establish preliminary indications of effectiveness; and to identify -- and adapt CfD in the light of -- potential mechanisms of change.

Setting

IAPT

With the roll-out of CfD, albeit at relatively low levels, through the IAPT programme, several informants felt that this would make the ideal setting for a trial of this type. This is the approach adopted by psychodynamic colleagues aiming to evaluate Dynamic Interpersonal Therapy (DIT), a therapeutic intervention which has a similar status to counselling within NICE depression guidelines and the IAPT programme. CfD-trained counsellors could be used to deliver the intervention with their normal patient group (albeit those meeting criteria for depression and willing to participate

in a trial), dramatically reducing intervention and assessment costs, as well as the challenge of identifying and recruiting eligible participants.

There was also a general feeling that the trial should be conducted in primary, rather than secondary, care, given that this was the site of most treatment for depression; and the means by which a study could add to the current body of evidence for counselling [14].

Given the numbers needed for such a trial, it was emphasised that this study would almost certainly need to be multi-site.

Informants associated within IAPT were very welcoming of such an approach. However, they emphasised that such a study would need to be developed in association with local IAPT services who were buying in to CfD training and delivery, as opposed to a collaboration with the national IAPT team, who they did not feel had the authority to implement such a trial.

Two limits of such a design, however, should be highlighted. First, as indicated above, numbers of CfD trained counsellors are likely to be quite low -- approximately 90 in 2011 -- and are expected to be widely dispersed across the UK. This could make coordination of counsellors and participants in the trial difficult. The ideal, therefore, would be the emergence of IAPT services with small clusters of counsellors delivering CfD, who would all see participants as part of the trial. Second and more widely, though, studies of psychological interventions in primary care -- whether counselling or other interventions -- do not tend to show strong effects; perhaps due to the high number of participants whose difficulties are milder and more due to external factors (e.g., finances) than internal ones (e.g., maladaptive emotional schemes). Hence, a trial of CfD in primary care may show less efficacy than if such a trial was conducted in a University or clinical setting, using more severely depressed clients.

Alternative settings

One informant felt that locating the trial within voluntary, non-health settings -- for instance, counselling centres -- would be more likely to demonstrate the effectiveness of counselling, being 'home ground'. S/he felt that a NHS setting would work against CfD, given that humanistic approaches are not normally orientated around diagnoses and a focus on clinical recovery.

Another informant raised the possibility of running the trial in a University clinic setting, which would be accessed by members of the public meeting criteria for depression. The advantage of such a setting might be greater control over the delivery and context of the intervention, making the trial more of an efficacy RCT than a pragmatic one. Disadvantages of such a setting, however, might be greater difficulty in recruiting participants, greater costs (as treatment costs would need to be covered, unless students were used), and findings that would be less representative of CfD in actual clinical settings.

Design/comparator condition(s)

A key issue discussed with all informants was the basic design for the study and the most appropriate comparator condition: in particular, whether CfD should be

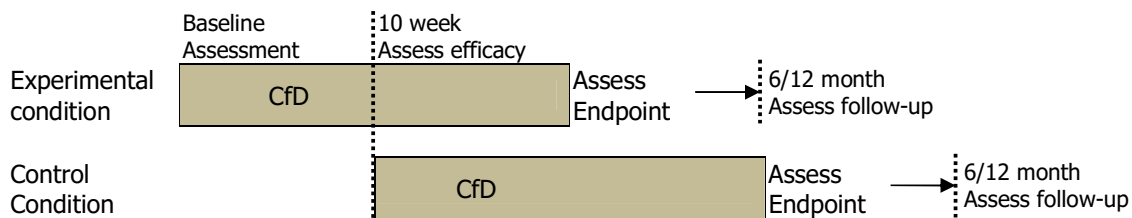
compared against a relatively non-active condition, such as waitlist; or whether it should be compared against an alternative therapeutic intervention such as CBT.

CfD versus waiting list/GP care as usual

Several informants indicated that they felt the first, and most pressing, step in evaluating CfD would be to demonstrate its basic effectiveness by testing it against a non-active condition such as wait list/delayed treatment or 'GP care as usual' (GPAU)/'best available GP Care'. It was argued that, for NICE/SIGN guidelines or for IAPT, a simple demonstration of superiority over no intervention was all that was needed; and that such a study would be far easier and cheaper to conduct -- particularly if located in IAPT -- than a more complicated and 'definitive' design.

A basic design proposed by one informant was to randomise participants to either immediate CfD or an 8 - 12 week CfD waiting list (see Figure 1). The efficacy of CfD could then be evaluated by assessment of both groups at 8 - 12 weeks, and the effectiveness of CfD could then be evaluated by comparing changes at endpoint and follow-up to baseline on a *within group* (i.e., cohort, rather than randomised) basis.

Figure 1: Comparison of CfD against waiting list



This simple wait-list design has been used to evaluate the effectiveness of cognitive therapy for PTSD related to terrorism and was accepted for publication in the *BMJ* [15]; though its publication post the 2005 NICE guidelines on PTSD mean that it is not clear whether such a design would be sufficient to enter into clinical guidelines. It is also similar to the design adopted by colleagues evaluating DIT.

With respect to a waiting list condition, however, several informants raised the issue of whether it is ethical to withhold treatment from depressed clients, particularly where there are therapies, such as CBT, that are now established as effective for this problem. On this basis, some informants felt that an ethics committee would not approve such a study. A majority, however, felt that such a study could be approved as ethical, provided that waiting time were no longer than normal periods of referral to treatment wait within a service; and standard exclusion criteria were used, such as participants with suicidal ideation and intent. It was argued, therefore, that a wait of eight to 12 weeks for a high intensity IAPT intervention would not be considered unreasonable; and, within Scotland, where a HEAT Target of a maximum 18 weeks from referral to treatment has recently been set (<http://www.18weeks.scot.nhs.uk/>), a slightly longer delay for treatment may still be in line with normal expectations. Furthermore, some informants felt that it was not unethical to allocate participants to a no-treatment, GP Care as Usual

condition, on the grounds that the evidence for the efficacy of psychological interventions in primary care was still uncertain. The ACUDep study, discussed above, was cited as one example of a depression trial in which a GPAU arm has recently received ethical approval.

With respect to NICE and SIGN guidelines, however, a more serious problem with the above 8 - 12 week waitlist design might be the lack of comparative follow-up data. Change from baseline to endpoint and follow-up could be evaluated, but without being able to compare changes at follow-up of one year or more between intervention and control groups, it would not be possible to establish the long-term efficacy of the treatment. In addition, without this data, a full health economics analysis would not be possible.

Along these lines, other informants felt that a comparison of CfD against no treatment would not be taken seriously; simply showing that something was better than nothing and potentially wholly attributable to a placebo effect.

CfD versus placebo

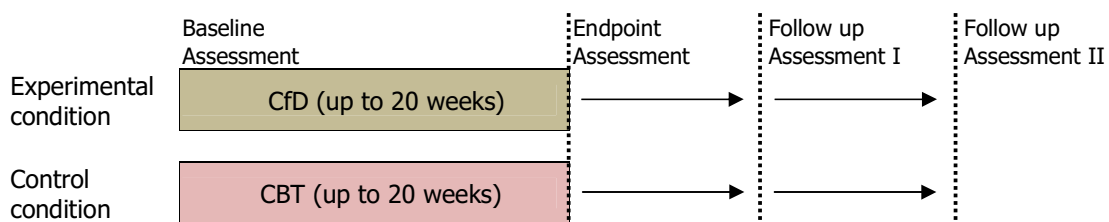
A couple of informants suggested that CfD might be compared against a more active placebo condition, such as supportive listening or a one hour talk to a CPN.

CfD versus CBT

Most participants felt that the most meaningful test of CfD, and the one most likely to influence NICE, SIGN and international guidelines, would be a comparative trial of CfD against CBT. Some saw this as a study to be conducted after an initial trial of CfD against waitlist/GPAU; others felt that there was sufficient evidence for CfD, and such urgency, that this comparative trial should be the principal focus of BACP efforts 'from the off'. CBT was favoured by many informants as it was the 'bog standard' treatment for depression: the established benchmark against which any other therapy needed to demonstrate its worth.

In Figure 2, the basic design for such a study is presented. Participants would be randomised to either CfD or CBT, receive up to 20 weeks of therapy, and then would be assessed at endpoint and a series of follow-up points to compare outcomes. The basic advantages of such a design is that it overcomes any ethical issues, as all participants receive a therapeutic intervention; and allows for follow-up assessments over an extended period of time. Such a study would also have the potential to be run in IAPT services, where both CfD and CBT are delivered.

Figure 2: Comparison of CfD against CBT



The basic disadvantage of such a study, however, is the numbers of participants needed to give it adequate statistical power, and the consequent costs and

complexities of such a design. Studies that compare psychological therapies against relatively inactive conditions, such as the waiting list design above, can expect fairly large effect sizes, and hence the numbers required to detect such differences are comparatively low (perhaps 50 to 100 in each condition). However, it is acknowledged that any differences between two active treatments are likely to be relatively small; and hence a study powered to detect whether or not one therapy is equivalent to another (an 'equivalence' design) or not significantly inferior to it (a 'non-inferiority' design) require much large numbers (perhaps 200 to 300 per condition). This, then, has major implications for the resources and funding needed to support such a trial.

It should also be noted that a study of this type, as developed by Michael King and colleagues (see above), was rejected for funding by the HTA.

CfD versus alternative evidence-based treatment

A couple of informants raised the possibility that, rather than testing CfD against CBT, it could be tested against an alternative NICE/SIGN-recommended treatment for depression, such as interpersonal therapy (IPT) or behavioural activation (BA). Although these therapies tend to be less well known, and their evidence-base may be less robust than for CBT, the principal advantage of such an approach could be that researchers and practitioners of these treatments may be more highly motivated to collaborate in such a study, because of their own need to develop their evidence-base. Indeed, it may be that researchers associated with these treatments are already in the process of developing their own RCTs, onto which it might be possible to 'piggy back' a CfD condition (along the lines of the ACUDep study, discussed above).

CfD versus an alternative humanistic treatment

One informant raised the possibility of comparing CfD against another humanistic therapy, such as emotion-focused therapy (EFT). It was suggested that, scientifically, this comparison between two relatively similar therapies would be much more meaningful than a comparison of two widely differing therapies (such as CfD and BA) where, in the latter case, it becomes almost impossible to identify the actual mechanisms of change. By contrast a trial, for instance, of a relational-based humanistic therapy versus a more technique-based humanistic therapy could help to isolate the relative effectiveness of relational versus technical practices.

CfD versus active treatment versus inactive condition (3-arm trial)

Comparing CfD against both an active therapy (e.g., CBT) and against an 'inactive' condition (such as GPAU) (as in the original King et al. (2000) study) provides a highly rigorous means of evaluating its effectiveness: both relative to other therapies and at a more absolute level. This is essentially the research design recommended in the NICE guidelines, comparing counselling against low intensity cognitive-behavioural interventions and treatment as usual (for the treatment of subthreshold and mild depression). However, few informants directly suggested or recommended such a design. This is probably due to its expense and complexity -- particularly if powered to identify small differences in effect between the two active conditions --

that goes well beyond what would be required to produce NICE and SIGN-relevant evidence.

5-arm trial

Based on the gold standard of RCT research in the pharmacological field, one participant suggested a five arm design with the following conditions: 1. CfD; 2. Placebo medication; 3. Standard antidepressants; 4. CfD + placebo medication; 5. CfD + Standard antidepressant. It was acknowledged, however, that this was a very complex design, and probably more aspirational than achievable at this point.

Client group

Level of depression

All informants agreed that, to be recommended within NICE, SIGN and/or other guidelines, it was essential that any trial was conducted with a clearly-defined clinical population, diagnosed with depression through the use of a standardised measure or assessment schedule.

However, while NICE recommends that the comparative effectiveness of counselling should be evaluated in the subthreshold and mild depression bands, the majority of informants felt that CfD should be tested with more clinically depressed clients: those diagnosed with mild, moderate and/or severe depression. Here, it was pointed out by several informants that the rate of 'spontaneous remission' increases as the level of mental distress decreases, such that it becomes very difficult to demonstrate the effectiveness of treatments in a mildly distressed population, over and above the naturally-occurring improvement that would be expected to take place in a waiting list or GPAU condition.

Specific client groups

There were various suggestions for specific subgroups within the depressed population that CfD might be trialled with. One possible advantage here could be that, if this was a group for which no evidence of effectiveness was available (e.g., students at a health centre), it might be considered less unethical to allocate participants to a no-treatment condition. Specific subgroups that were suggested were:

- People on long term sickness, absence and/or incapacity to work. It was suggested that the Department for Work and Pensions (DWP) might be interested in supporting such a study.
- Clients who have failed to respond to CBT, or other evidence-based treatments.
- Clients who have been found, through preliminary research [e.g., the 'Glover Report', 16] to show the greatest comparative improvement in counselling (e.g., clients who have experienced 'family loss').
- Clients with mixed anxiety and depression -- for whom counselling has already been shown to be effective.

Analysis of individual differences

Several informants felt that, in any study, it would be important to assess the kinds of clients for whom CfD was particularly effective or ineffective. This might be particular factors such as:

- Severity of level of depression.
- 'Personality' characteristics: e.g., reactance/resistance, internalising coping style [both of which have been associated with better outcomes in less directive therapies, see 17], perfectionism.

POTENTIAL FUNDERS

A range of potential funders for this trial were identified. However, most informants felt that research funding was becoming more and more difficult in the present financial climate, and were not optimistic about such a trial receiving large-scale funding.

National Institute of Health Research (NIHR) -- Health Technology Assessment (HTA) programme: Clinical Evaluation and Trials funding stream

This stream 'funds grants for evaluation studies and clinical trials supporting research that is immediately useful to clinical practice and decision makers in the NHS' (<http://www.hta.ac.uk/funding/clinicaltrials/index.shtml>). Funded studies tend to be large/multisite, based in 'real life' NHS settings, with a pragmatic RCT design, and a focus on long term effectiveness and a health economics analysis. There are no restrictions of costs on a proposed project. This would, probably, be the most appropriate and relevant source of funding for a trial of CfD in the NHS -- particularly if compared against CBT or another active treatment. However, as noted above, a proposed trial of counselling for depression was submitted by Michael King and colleagues to this funding stream in 2009, and rejected at the initial stages of application.

NIHR and Medical Research Council (MRC) -- Efficacy and Mechanism Evaluation (EME) Programme

'The EME programme is broadly aimed at supporting "science driven" studies with an expectation of substantial health gain. The clinical studies are likely to be mostly randomised controlled trials but other forms of evaluation appropriate for the intervention under study will also be supported' (<http://www.eme.ac.uk/about/>). There are no restrictions of costs on a proposed project. Compared with the HTA, the EME tends to fund smaller studies, with treatments at an earlier stage of development. This could make it particularly appropriate for funding of a waiting list design (see Figure 1). However, there is also a particular emphasis on explanatory/efficacy studies, testing the intervention under ideal conditions, rather than the 'real world' conditions of IAPT services.

NIHR -- Programme Grants for Applied Research

This is 'a national response mode programme that aims to provide evidence to improve health outcomes in England through promotion of health, prevention of ill health, and optimal disease management (including safety and quality), with particular emphasis on conditions causing significant disease burden' (<http://www.ccf.nihr.ac.uk/Pages/Home.aspx>). Funding is for a linked series of investigations rather than just one study, and needs to be led by NHS-located colleagues, which may make it less appropriate for the present trial. 'Individual awards are for a maximum of £2 million over a period of three to five years.'

Chief Scientist Office (CSO)

The CSO, 'part of the Scottish Government Health Directorates, supports and promotes high quality research aimed at improving the quality and cost-effectiveness of services offered by NHSScotland and securing lasting improvements to the health of the people of Scotland' (<http://www.csoscot.nhs.uk/>). For psychological therapy researchers in Scotland, the CSO is a common first 'port of call' for funding, and can fund research across the UK, though the 'Principal Applicant must be a permanent salaried member of staff in a Scottish Institution.' 'Project grants are normally limited up to a maximum of £225,000,' which is likely to be insufficient for any major trial of CfD.

Wellcome Trust

Wellcome Trust Senior Investigator Awards 'Support exceptional, world-class researchers, who hold an established academic position and have a compelling long-term vision for their research' (<http://www.wellcome.ac.uk/Funding/investigator-awards/index.htm>). These awards are offered to individual academics and cover direct costs only (for instance, research assistants), in the range of £100k to £425k per year. In relation to CfD, such an award would require an established, UK-based academic to develop an extended programme of research into CfD which could include, but should not be limited to, an RCT.

Alternative funders

Informants suggested a range of other potential sources of funding or part-funding that may be worthy of further exploration:

- National Institute of Mental Health: the major US-based funding agency for mental health interventions; collaboration with US-based researchers would be required (<http://www.nimh.nih.gov/index.shtml>).
- Leverhulme Trust: funding for lead academics for areas that may not be covered by other major grant-making bodies (<http://www.leverhulme.ac.uk/>)
- European Commission funding: Seventh Programme Framework (http://cordis.europa.eu/fp7/home_en.html)
- Mental health charities, particularly those linked to depression, such as the Depression Alliance (<http://www.depressionalliance.org/>)

BACP funding

In March 2011, the BACP Board of Governor's agreed to approve £150k for the budget year 2011/12 for the first year of a three year programme, which will see circa £450k committed to developing an RCT of counselling for depression.

A trial funded by a charity such as BACP could have significant cost advantages; as university-based researchers would be expected to cost for direct costs only, as opposed to full economic costing or 80% FEC, as with most funding councils.

RESEARCH TEAM

Lead investigator

Some informants felt that it would be essential for the lead investigator(s) of such a project to be sympathetic to counselling/person-centred experiential therapy. However, they would also need to be experienced triallists, drastically reducing the numbers of people who could potentially lead on such a project.

Counselling-based academics

Around 15 academics from within the UK counselling field expressed a potential interest in being involved in such a study (details available on request). In nearly all cases, experience of controlled trials is likely to be limited; however, such colleagues might serve a valuable role in helping to develop and deliver such a study.

Non-humanistic colleagues

Several informants emphasised the importance of involving in the trial academics associated with non-humanistic therapies, particularly if CfD was to be compared against an alternative active treatment. This, it was emphasised, would be essential to ensure that any comparative condition would not be challenged or questioned at the end of the study.

Methodologists

The need to involve a strong methodologist in the study was also highlighted.

Service users

Involving service users 'from the ground up' was emphasised by some of the informants, and particularly those representatives of the particular mental health area, such as Depression Alliance or Depression Alliance Scotland.

Primary care providers

Providers of primary care, such as Heads of Psychological Therapy Services or GPs, would be essential to involve in a trial of this type; and would be key to the success of the project.

Members of the person-centred experiential community

Preliminary interest in the trial was expressed by representatives of the three main person-centred organisations relevant to a UK context:

- British Association for the Person-centred Approach (BAPCA).
- Person-centred Therapy Scotland (PCT Scotland).
- World Association for Person-centered and Experiential Psychotherapy and Counselling (WAPCEPC).

ADDITIONAL/ALTERNATIVE STRATEGIES FOR DEVELOPING THE EMPIRICAL STATUS OF COUNSELLING

This section draws together additional suggestions and ideas for developing the status of counselling as an empirically-based or validated therapy.

Large cohort study

As indicated above, some informants did feel that a cohort study, if of sufficient size and rigour, could have the potential to influence NICE/SIGN guidelines. The inclusion of CfD in some IAPT services, with the collection of a minimum dataset, offers the ideal opportunity to develop such a dataset. In addition, humanistic counsellors external to IAPT, providing that they followed appropriate procedures, would also have the potential to contribute to such a study. This is something that might be coordinated through a Practitioner Research Network (PRN), potentially based at BACP. Key criteria for such a study would be:

- Good baseline descriptions of clients: e.g., demographics, length of depression, employment status.
- Diagnosis through some systematic procedures, such as the PHQ.
- A minimum of missing data.
- Audio recording of a random selection of sessions, for evaluating fidelity to treatment model.
- All practitioners to work according to CfD manual; and to have some shared, systematic training.
- Use of a brief outcome scale, such as the BDI, at regular intervals.
- Some independent (i.e., without therapist involvement) assessment of difficulties (for instance, forms completed after sessions and posted back to researchers).

Developing a culture of conducting RCTs in the counselling community

Ultimately, if predictions regarding the continued importance of RCTs are correct, then there will need to be more than just one RCT of CfD to secure the long term future of counselling. Rather, a programme of ongoing RCT research will be required, which can serve to establish counselling as an evidence-based treatment

for a variety of psychological difficulties. As one informant stated, the unit of analysis for NICE and SIGN is no longer individual trials, but *groups* of trials, with the focus on adding data to increasingly large meta-analysis. However, as the history of psychotherapy research would seem to suggest, there are very few academics outside of the counselling community who would seem to be interested in developing the evidence-base for this approach. If the counselling community wants to sustain its own future, therefore, it would seem to be essential to develop, internally, a culture in which researchers, academics and students are far more likely to conduct RCTs than they are at present.

This is a major challenge for two reasons. First, members of the counselling community, with their philosophical and political leanings towards humanism, tend to be relatively hostile to experimental methodologies. Second, undertaking a randomised controlled trial is a major feat and expense, well beyond the grasp of most students -- let alone academics -- within the counselling field.

How, then, might an organisation like BACP raise the level of interest and engagement of its community in RCT studies? First, it may be that it needs to communicate to its members, as identified in this paper, that RCT evidence is likely to remain key to the commissioning and funding of services and that, without RCT evidence, a therapy may increasingly struggle for public support. Second, it can inform its members more about RCTs: what they are, what they can tell us about, and what their limitations are as well as their strengths. Third, it can encourage academics within the counselling community to consider, more seriously, the possibility of developing RCTs of counselling for particular forms of psychological distress (for instance, grief or interpersonal problems). Fourth, it can encourage academic supervisors to consider supporting their students in conducting such studies. Clearly, as indicated above, a fully-powered RCT will be beyond the reach of most, and funding is extremely difficult to come by; but small-scale pilot RCTs by either academics or PhD-level students are feasible, and can set the groundwork for subsequent funding bids for a larger trial.

Collaboration with user organisations

One informant felt that the best way forward for the counselling community was to develop closer links with user organisations and the mental health charities, who he felt would have increasing levels of influence in the years to come. Such alliances would then have more authority to challenge the established 'hierarchy of evidence' and lobby for a wider evidence-base to be used in the development of clinical guidelines. However, the extent to which service user organisations are critical of the established 'hierarchy of evidence' -- and would be willing to collaborate in such an alliance -- is uncertain.

Direct appeal to service providers

A couple of informants noted that, with the recent UK government moves towards localisation of NHS decision making [11], the power of centralised bodies such as NICE and SIGN may be substantially attenuated. Instead, GP consortia will have the power to commission services -- with an increased role for patients' personalised preferences, choices and feedback -- and this could mean that professional bodies

will have increased power to directly influence commissioners. An alternative/additional strategy for BACP, therefore, might be to set up systems to directly communicate with GPs and members of the public about the potential value of counselling: for instance, public information websites, leaflets and media campaigns.

Challenging clinical guidelines and hierarchies of evidence

In general, participants from the BACP did not feel that this strategy had proved particularly useful, despite exhaustive efforts, and did not identify it as a potentially productive strategy for the future.

SWOT ANALYSIS

What are the strengths, weaknesses, opportunities and threats for the BACP in developing an RCT of CfD, and a more broadly positive attitude towards RCTs in the counselling community? Some preliminary suggestions are as follows:

Strengths

- The recent development of a diagnosis-specific, manualisable counselling intervention (CfD); as well as an associated measure for auditing fidelity to treatment [the Person-centred and Experiential Psychotherapy Scale, 18].
- The existence of an efficient, effective, well-managed coordinating body (BACP) with the potential of available funds.
- Large numbers of counselling research students, who could be encouraged to consider focusing their efforts towards controlled studies.
- A counselling community that cares passionately about its work; and that may be increasingly motivated to develop its evidence-base as it feels more and more under threat.
- An intervention that may be experienced by clients as particularly gratifying.

Weaknesses

- A strong disinclination, amongst members of the counselling and person-centred experiential community, to engage in RCT research.
- Counselling academics have very little experience of, or confidence in undertaking, RCT methods.
- Potential splits within the counselling, and even person-centred experiential community, over what an effective counselling for depression should look like.
- 'Counselling' tends to be UK-based, with few international links/potential for collaboration.
- An urgent need to demonstrate effectiveness, which may make the counselling community less open to findings which challenge -- but may ultimately help to improve -- the effectiveness of its intervention.

Opportunities

- The roll-out of CfD in the IAPT programme.
- Genuine goodwill from members of the wider psychological therapies community towards the evaluation of counselling and humanistic therapies.

Threats

- The rapid development, and improvement, of the evidence-base for non-counselling psychological interventions, meaning:
 - The amount, and quality, of evidence required for CfD to demonstrate its comparative worth is constantly increasing;
 - Trials against inactive or no treatment controls become increasingly ethically problematic.
- Lack of funding opportunities.
- The general lack of evidence of efficacy for primary care-based interventions.
- Counselling may be seen as 'old hat' and not of interest to funders.
- Confusion over the term 'counselling': is it a particular form of humanistic therapy (as in CfD) or an umbrella term for a range of psychotherapeutic interventions?

CONCLUSION

From discussions with leading experts in the field, it is clear that the need for RCT evidence will not abate in the short to medium term future. Without it, it seems increasingly likely that counselling will be pushed to the margins of NHS service delivery, and if no further RCT evidence is produced by the next iteration of NICE depression guidelines, it may well be entirely supplanted by other RCT-evidenced treatments. In terms of developing RCT evidence for counselling, however, the emergence -- and roll out -- of CfD provides a unique opportunity to develop the evidence-base. Two strategies for trialling CfD, by no means mutually exclusive, would seem most promising. First, to secure CfD for the short term, BACP should look towards establishing a trial of CfD against waiting list, as situated in IAPT, and outlined in Figure 1. Second, to establish the long-term effectiveness of CfD, and to secure its place in NICE/SIGN guidelines, it should look towards conducting a comparative trial of CfD against CBT (see Figure 2). Pilot studies for one or both these designs may be advisable.

RECOMMENDATIONS

1. BACP should establish a CfD RCT 'Task Force'. This should be led by the BACP Research Department, with the possibility of including representatives from a range of stakeholder groups, such as primary care providers, service users, experienced triallists, counselling/PCE academics, and PCE practitioner organisations. Its objectives should be:

- a. To progress a trial of CfD against waiting list, or GP care as usual, in IAPT services (with consideration for an initial pilot study).
 - b. To work towards the development of a funding bid for a larger trial of CfD against CBT (with consideration for trialling an initial pilot study).
2. The research department at BACP, in conjunction with the editors of its publications *Counselling Psychotherapy Research* and *Therapy Today*, should look towards means of creating a more RCT-knowledgeable and -friendly culture within the UK counselling community.

REFERENCES

1. National Collaborating Centre for Mental Health, *Depression: The NICE guidelines on the treatment and management of depression in adults*, in *Clinical Guideline CG90*. 2010, National Institute for Health and Clinical Excellence: London.
2. National Collaborating Centre for Mental Health, *Depression in adults with a chronic physical health problem: Treatment and management*, in *Clinical Guideline CG91*. 2009, National Institute for Health and Clinical Excellence: London.
3. Scottish Intercollegiate Guidelines Network, *Non-pharmaceutical management of depression in adults: A national clinical guideline*. 2010, Scottish Intercollegiate Guidelines Network: Edinburgh.
4. Scottish Government, *Mental health in Scotland: A Guide to delivering evidence-based Psychological Therapies in Scotland -- "The Matrix"*. 2008, The Scottish Government: Edinburgh.
5. Elliott, R. and E. Freire, *The effectiveness of person-centred and experiential therapies: A review of the meta-analyses*, in *Person-centred and experiential therapies work: A review of the research on counseling, psychotherapy and related practices* in M. Cooper, J.C. Watson, and D. Hölldampf, Editors. 2010, PCCS: Ross-on-Wye. pp. 1-15.
6. Simpson, S., et al., *A randomized controlled trial to evaluate the effectiveness and cost-effectiveness of counselling patients with chronic depression*. Health Technology Assessment, 2000. **4**(36).
7. Watson, J.C., et al., *Comparing the effectiveness of process-experiential with cognitive-behavioral psychotherapy in the treatment of depression*. Journal of Consulting and Clinical Psychology, 2003. **71**(4): p. 773-781.
8. King, M., et al., *Randomised controlled trial of non-directive counselling, cognitive-behaviour therapy and usual general practitioner care in the management of depression as well as mixed anxiety and depression in primary care*. Health Technology Assessment, 2000. **4**(19): p. 1-83.
9. Roth, A., A. Hill, and S. Pilling, *The competences required to deliver effective Humanistic Psychological Therapies 2009*, University College London: London.
10. Hill, A., *The competences required to deliver effective Counselling for Depression (CfD) 2010*, British Association for Counselling and Psychotherapy: Lutterworth.
11. Department of Health, *Equity and excellence: Liberating the NHS*. 2010, Department of Health: London.
12. Davies, P., et al., *Humanistic therapies versus treatment as usual for depression (Protocol)*, in *Cochrane Library*. 2010.
13. Churchill, R., et al., *Humanistic therapies versus other psychological therapies for depression (Protocol)*, in *Cochrane Library*. 2010.
14. Bower, P., et al., *Effectiveness and cost effectiveness of counselling in primary care (Cochrane Review)*, in *The Cochrane Library, Issue 1*. 2003, Update Software: Oxford.
15. Duffy, M., K. Gillespie, and D.M. Clark, *Post-traumatic stress disorder in the context of terrorism and other civil conflict in Northern Ireland: randomised controlled trial*. BMJ, 2007. **334**(7604): p. 1147.

16. Glover, G., M. Webb, and F. Evison, *Improving Access to Psychological Therapies: A review of the progress made by sites in the first rollout year*. 2010, North East Public Health Observatory: Stockton on Tees.
17. Beutler, L.E., et al., *Participant factors in treating dysphoric disorders*, in *Principles of Therapeutic Change that Work*, L.G. Castonguay and L.E. Beutler, Editors. 2006, Oxford University Press: Oxford. p. 13-63.
18. Freire, E., R. Elliott, and G. Westwell, *Development and validation of an adherence/competence measure for person-centred and experiential psychotherapies*, in *8th World Conference for Person-Centered and Experiential Psychotherapy and Counseling*. 2010: Rome, Italy.