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319

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A systematic review of motivational interviewing in physical health care settings

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Purpose. Motivational interviewing (MI), a method of augmenting an individual's motivation to change problematic behaviours, is a patient-centred counselling style that seeks to help patients resolve ambivalence about behaviour change. MI has successfully been used in the field of addictions and has recently received increased interest as a means of promoting treatment adherence in physical health care settings. This systematic review is aimed to evaluate the effectiveness of MI interventions in physical health care settings.

Methods. Electronic databases were searched for articles specifying the use of 'motivational interviewing' in physical health care settings between 1966 and April 2004. Fifty-one relevant abstracts were yielded and data was extracted from eight relevant selected studies.

Results. Eight studies were identified in the fields of diabetes, asthma, hypertension, hyperlipidaemia, and heart disease. The majority of studies found positive results for effects of MI on psychological, physiological, and life-style change outcomes. Problems with research in this area include: small sample sizes, lack of power, use of disparate multiple outcomes, inadequate validation of questionnaires, poorly-defined therapy and training.

Conclusions. While MI has high face validity across a number of domains in physical health care settings, the general quality of trials in this area is inadequate and therefore recommendations for its dissemination in this area cannot yet be made. More research into MI applied to health behaviour change is urgently required.

Motivational interviewing

Motivational interviewing (MI) is a method of augmenting an individual's motivation to change problematic behaviours. It is a directive, client-centred counselling style that seeks to help clients explore and resolve ambivalence about behaviour change (Rollnick & Miller, 1995). It has been described as 'the polar-opposite of advice giving' (Rollnick, Heather, & Bell, 1992) and sets out to identify how 'ready, willing, and able' a

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320 K. M. Knight et al.

person is to change, and counsel them accordingly. It is an evidence-based practical, person-centred counselling approach based on Prochaska and DiClemente's (1984) transtheoretical model of behaviour change. For a more in-depth description of MI the reader is referred to Miller and Rollnick (1991).

MI has been widely used in the field of addictions and substance abuse and a recent systematic review found substantial evidence that MI is an effective substance abuse intervention method when used by clinicians who are non-specialists in substance abuse treatment (Dunn, Deroo, & Rivara, 2001). Problems with behaviour change and resistance, however, are clearly not confined to the addictions field (Rollnick, 2001). MI has been used in enhancing compliance with medication in adults with schizophrenia (Bellack & DiClemente, 1999); for the treatment of eating disorders (Killick & Allen, 1997; Treasure & Ward, 1997); and to promote healthy life-styles in a number of settings from stopping smoking (Ershoff *et al.*, 1999), improving dietary adherence (healthy eating) in adolescents (Berg-Smith *et al.*, 1999), increasing fruit and vegetable intake (Resnicow *et al.*, 2001), to promoting mammography participation (Ludman, Curry, Meyer, & Taplin, 1999).

MI has, however, more recently been receiving increased interest as a means of promoting treatment adherence in physical health care settings such as hypertension, asthma, and diabetes (Britt, Hudson, & Blampied, 2004). This systematic review therefore aimed to evaluate the effectiveness of MI interventions within these health care settings.

Searching the literature for completed reviews in this area yielded one systematic review examining the effectiveness of interventions based on a 'stage of change' approach to promote individual behaviour change in health care settings (Riemsma *et al.*, 2002) and a number of other review articles. These included: issues of adherence in chronic disease (Konkle-Parker, 2001); the use of the transtheoretical model of behaviour change in facilitating behaviour change in chronic illness (Cassidy, 1999); opportunities and limitations of adapting MI in health care settings (Emmons & Rollnick, 2001); and an overview of MI with particular reference to its application to health problems (Britt *et al.*, 2004). Not including substance abuse, no review articles were found that have systematically examined the effectiveness and extent to which MI has been used in different physical health care settings to date.

Aims

We therefore aimed to systematically review studies using MI in physical health care settings to:

- identify the extent to which MI has been used in different physical health settings;
- appraise the effectiveness of MI when used in subjects with physical health problems (excluding substance abuse) and identify effective outcomes;
- provide an overview of the research quality;
- identify further research needs in this area.

Method

Selection of studies for inclusion

A search of the following electronic databases were used to identify relevant papers for inclusion in the review: Amed 1985-Jan 2005; Cinahl 1982-April 2004; Embase 1980-April 2004; Medline 1966-April 2004; Psych info 1974-April 2004; and ISI Web of

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A systematic review of motivational interviewing in physical health care settings

Science 1990–2004; and SIGLE 1980–2004. The Cochrane Library, National Research Register (NRR), Dissertation Abstracts International, Health Technology Assessment (HTA), and Commission for Health Improvement (CHI) websites were also searched for studies, which could be included in the review using the keywords 'motivational interviewing'. Searches were conducted in August 2002 and subsequently updated in September 2003 and April 2004.

Keywords included 'motivational interviewing' as well as 'stages of change', 'transtheoretical model', 'behaviour change' and 'client centred counselling' to ensure papers not explicitly advertising the use of MI would be included. A comprehensive list of common physical-health illnesses was included alongside the medical subject headings (MeSH) for 'chronic illness' including all subheadings.

Only English language articles were used. Key researchers and those people currently conducting work in progress identified from the National Research Register (NRR) were contacted directly for unpublished materials and for any other information they could provide for help with the review. The grey literature was searched using the database SIGLE (as shown above), and searching CINAHL and Dissertation Abstracts International gave us the opportunity to identify dissertations and theses and other unpublished research. Conference proceedings were scrutinized using ISI Web of Science (as shown above). The following journals were hand-searched for relevant articles from 2002 to the time of this review going for publication: *American Journal of Preventative Medicine*, *British Journal of Clinical Psychology, Clinical and Experimental Pharmacology and Physiology, Diabetes Care, Journal of Clinical Psychology in Medical Settings, Journal of Consulting and Clinical Psychology, and Patient Education and Counselling*.

Search selection

The search procedure yielded 467 papers, of which 187 were duplicates.

The remaining 280 abstracts were then examined using the following inclusion criteria:

- Population patients suffering from, or those patients at risk of, developing a
 common physical illness (including, for example, hyperlipidaemia and hyperten
 sion). (HIV was excluded because after reviewing a number of studies it became
 clear that most included patients with substance abuse problems, which was an
 important focus of treatment).
- Interventions studies specifying the use of 'motivational interviewing' as an intervention to promote behaviour change.
- Outcomes no specific criteria for outcomes were set as the aim of the review was to identify and collate all effective outcomes.
- Study designs due to small numbers of randomized controlled trials (RCTs) in this
 area, non-randomized as well as non-controlled studies were scrutinized for
 inclusion in the review.

Paper retrieval

Fifty-one potentially relevant abstracts were identified and the full papers were retrieved for more detailed information.

• Twenty-five were excluded and categorized as background papers: (4 studies dealing with health professional training, 12 review papers, 8 studies still in

321

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322 K. M. Knight et al.

progress. One pilot qualitative article could not be included in the review as it combined MI with narrative therapy, and was therefore not a pure MI intervention suitable for inclusion in this systematic review).

- Eighteen studies were excluded because they did not involve MI and/or a common physical illness.
- Eight studies were selected as relevant papers and were included for descriptive analysis in the systematic review.

To minimize bias in the selection procedure a second researcher (LM^c) examined the 51 potentially relevant papers and any discrepancies were discussed until a balanced decision was reached.

The reference lists of the 51 selected papers were further scrutinized for any additional studies and the Social Sciences Citation Index (SSCI) was searched for any additional papers referencing the eight selected papers.

The key authors were also contacted by email or letter for more detailed information about the actual interventions delivered to allow us to comprehensively compare interventions across studies.

Data extraction

Data extraction sheets were first piloted and then amended before a standardized data extraction sheet was finalized. Reliability of data extraction was checked on a 60% subsample of the 51 originally selected reports. Accuracy of the data extraction procedure was determined by comparing data collected in the original extraction (KK) to that extracted by a second researcher (LM^c) and was found to be highly accurate, with complete concordance in 95% of checked data points.

Data synthesis

A descriptive account of the studies was formulated to characterize past research and to identify strengths and weaknesses in the literature. Due mainly to the disparity of outcome measures, but also to the variety of intervention time lengths, targeted problem behaviours, settings, and interventionists' backgrounds and skill levels, it was not considered statistically appropriate to combine outcomes in a meta-analysis.

Quality assessment

Quality control of the above studies was determined by what was reported in each article, and guided by the consort statement, a set of recommendations for improving the quality of reports of RCTs (Moher, Schulz, & Altman, 2001). The consort statement was used as a guideline because no instrument exists for the assessment of observational studies. Another frequently used tool, the 'Jadad', an instrument to measure the likelihood of bias in randomized controlled trials (Jadad, Moore, Carroll *et al.*, 1996) was not appropriate for use in the present review to assess quality of trials, as it is based on classic experimental RCTs (i.e. double-blind trials), which are not relevant to the nature of psychological interventions.

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A systematic review of motivational interviewing in physical health care settings

323

Results

Summary of studies

Table 1 shows a summary of the main characteristics of each study included in the review

This systematic review (see Table 1) yielded eight published articles that used MI in physical health care settings. These included three in diabetes (Channon, Smith, & Gregory, 2003) [1], (Clark & Hampson, 2001) [2], (Smith, Heckemeyer, Kratt, & Mason, 1997) [3], one in asthma (Schmaling, Blume, & Afari, 2001) [4], one in hyperlipidaemia (Mhurchu, Margetts, & Speller, 1998) [5], one in hypertension (Woollard *et al.*, 1995) [6], one for patients awaiting coronary artery bypass surgery (McHugh *et al.*, 2001) [7], and one in the area of cardiac rehabilitation (Scales, 1998) [8].

Design

Of the eight empirical papers included in this review, only four studies were RCTs. One was underpowered [5] and one considered baseline data only (included in the review for descriptive purposes) [2], leaving two adequately powered and completed randomized controlled trials [7 & 8], Of the remaining four papers, three were pilot studies [1, 3, & 4] and the other a non-random controlled trial [6].

The main aims of the studies were to compare the effectiveness of MI against or in addition to routine services and obtain data on the impact of MI on patient outcomes.

The two adequately powered and completed RCTs both found that MI was an effective intervention for improving care for patients in terms of helping patients to adopt healthier life-styles compared with existing services.

Table 2 highlights the overall effectiveness of outcomes from all eight studies. The column marked 'N' represents the number of studies including the variable in the methodology.

MI is shown (Table 2) from the studies included in this systematic review to yield some positive effects on the majority of psychological, life-style change, and physiological variables. By contrast, one or more study, however, found MI not to be effective in terms of improving knowledge, helping patients understand the role of the family process, increasing feelings of well-being, reducing alcohol intake, or improving adherence to prescribed medication. It should be noted, however, that results were not reported/specified for 37% (N=21) of the total number of variables measured across all the studies. This lack of reporting could be related to negative results.

Critique

Reporting of eligibility criteria and randomization

All three of the completed RCTs reported eligibility criteria and exclusion criteria [5, 7 & 8]. Of the remaining five studies, all reported eligibility criteria, with only three reporting exclusion criteria [1, 3 & 4,]. Methods of randomization were specified adequately in three of the RCTs [2, 5 & 8].

Power and sample size

In this systematic review, only one of the RCTs reported a sample size calculation based on power [5]. This particular study achieved 80% of the target sample size reducing the

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324 K. M. Knight et al.

Table 1. Main characteristics of the eight included studies in the systematic review

4	K. M.	Knight et al.		
	Comments	Pilot study. Small sample size. No control group – just comparison group. Sessions led by researcher	RCT – baseline data available only. Sessions led by interventionist/research psychologist. Method of randomization – random numbers table	Randomized pilot study. Low power. 4 months short follow-up. Small sample size. Method of randomization not specified. Sessions led by psychologists experienced in MI
	Outcomes	HbA I c significantly decreased ($p < .05$). Fear of hypoglycaemia significantly decreased ($p < .05$). Diabetes statistically significantly perceived as easier to live with for intervention group ($p < .05$)	Baseline data available only	Improved adherence to programme ($\rho = .01$), increased blood glucose testing ($\rho = .05$) and exercise ($\rho = .07$), and glycaemic control for intervention group vs. control group ($\rho = .02$)
	Interventions	Intervention Group: individual MI sessions (mean no. of 4.7). Control group: Comparison group only.	Intervention group: brief MI session plus 10 minutes FU phone calls at 1, 3, and 7 weeks post session. Control group: usual care	16; follow-up 4 months; Intervention group: 16 week Improved adherence to behavioural weight-control programme ($p=.01$), programme plus three MI increased blood glucose sessions. Control group: 16 testing ($p=.05$) and week behavioural weight- exercise ($p=.07$), and control programme glycaemic control for intervention group vs. control group ($p=.02$)
	N, follow-up interval, and mean age	N = 22; follow-up 6 months; Intervention Group: mean age 15.8 yrs individual MI session no. of 4.7). Control Comparison group o	N = 100; follow-up 1 yr; mean age 59.4 yrs	N = 16; follow-up 4 months; mean age 62.4 yrs
	Study ID Reference and reference population	Channon et al. (2003). Adolescents with Type I diabetes	Clark and Hampson (2001). Overweight adults with Type II diabetes	Smith <i>et al.</i> (1997). Overweight women with Type II diabetes
	Study ID reference	_	7	m

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A systematic review of motivational interviewing in physical health care settings 325

	A systematic revi	ew of motivational interviewing in physical	nealth care settings 325
Comments	Randomized controlled pilot study. Sessions led by masters level therapists. Low power and small sample size. Method of randomization not specified. 2 weeks short follow-up	RCT. Low power – 61%. Sessions led by dietician. Method of randomization – computer-generated random log	Controlled trial. Method of randomization not specified. Sessions led by nurse counsellor. 18 weeks – short follow-up
Outcomes	Increased levels of motivation ($p < .05$) and positive attitude towards adhering to medication ($p < .05$) for intervention group vs. control group	Statistically significant increases in reported dietary knowledge and behaviour ($\rho < .001$) and statistically significant reductions in body weight, energy intake, total and saturated fat in both control group and intervention group (no changes in serum cholesterol in intervention group or control group)	Statistically significant fall in blood pressure ($\rho < .05$) and weight ($\rho < .05$) for high intervention group and alcohol ($\rho < .05$) and salt intake ($\rho < .05$) for low intervention group vs. control group
Interventions	Intervention group: one session of brief education plus one session of MI. Control group: one session of brief education	N = 97; follow-up 6 months; Intervention group: three MI mean age not specified sessions at baseline, 6 weeks and 3 months. Control group: standard lipid lowering dietary advice at baseline, 6 weeks and 3 months	Intervention group: low group 15 minutes telephone contact, high group 45 minutes face-to-face – both contacted every 4 weeks for 18 weeks. Control group: usual care
N, follow-up interval, and mean age	N = 25; follow-up 2 weeks; mean age 39.32 yrs	N = 97; follow-up 6 months; mean age not specified	N = 146; follow-up 18 weeks; mean age 58 yrs
Reference and e population	Schmaling et al. (2001). Asthma	Mhurchu e <i>t al.</i> (1998). Patients with hyperlipidaemia	Woollard et al. (1995). Patients with hypertension
dy ID			

Table 1. (Continued)

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326 K. M. Knight et al.

Table I. (Continued)

	()					6
Study ID reference	Study ID Reference and reference population	N, follow-up interval, and mean age	Interventions	Outcomes	Comments	K. M.
7	McHugh et al. (2001). Patients awaiting coronary artery bypass surgery	N = 98; follow-up 15 months; Median age control group 63 yrs, median age intervention group 61.1 yrs	Intervention group: monthly shared care programme consisting of health education and MI. Control group: usual care	More likely to stop smoking $(p = .001)$, obesity $(p = .01)$ and mean total cholesterol $(p = .003)$ reduced target blood pressure $(p < .001)$, general health score $(p = .005)$, and levels of anxiety and depression improved $(p < .001)$ for ntervention group vs. control group	RCT. Method of randomly assigned. Sessions led by – community-based cardiac liaison nurse and general practice nurse	Knight et al.
ω	Scales (1998). Patients with coronary artery disease awaiting cardiac rehabilitation	N = 61; follow-up 12 weeks; Intervention group: mean age 59.6 yrs programme plus 1 Pland if 'ready to chathree (30 minutes e skills-based counsel sessions]. Control g traditional rehability programme consisting hour three times per supervised exercise plus eight (45 minut lectures with group discussion on heart plus optional life-sty behavioural interver	Intervention group: traditional rehabilitation programme plus I hour MI [and if 'ready to change' then three (30 minutes each) skills-based counselling sessions]. Control group: traditional rehabilitation programme consisting of I hour three times per week supervised exercise sessions plus eight (45 minutes) lectures with group discussion on heart disease plus optional life-style behavioural intervention	Statistically significant improvement for perceived stress ($p = .05$), physical activity ($p = .033$), and dietary fat intake ($p = .047$) at 12 weeks for intervention group vs. control group	RCT. Method of randomization —random numbers table. MI sessions led by — clinical psychologist	

Abbreviations: MI, motivational interviewing; N, number of subjects; RCT, randomized controlled trial.

A systematic review of motivational interviewing in physical health care settings

Table 2. Overall effectiveness of MI on the outcome variables measured in the studies included in the systematic review

Variable	N	MI effective	MI not effective	Not specified
Psychological – cognitive				
Readiness to change	4	3 ^a	0	I
Knowledge	3	l ^a	2	0
Self-efficacy	3	1	0	2
Personal models	2	1	0	I
Barriers to diabetes self-care	I	0	0	I
Role of family process	I	0	I	0
Binge eating severity	I	0	0	I
Subtotal	15	6	3	6
Psychological – emotional				
Well-being anxiety or depression	2	1	1	0
Quality of life	2	1	0	I
Self-esteem	I	0	0	I
Personality	I	0	0	I
Perceived stress	I	I	0	0
Subtotal	7	3	1	3
Life-style change				
Exercise	6	3	0	3
Alcohol intake	3	1	1	I
Smoking	3	1	0	2
Self-care behaviours	3	1	0	2
Fat intake	3	1	0	2
Nutrition	2	l ^a	0	I
Salt intake	I	1	0	0
Technique of metered dose inhalers	I	l ^a	0	0
Adherence to programme	I	I	0	0
Adherence to prescribed medication	I	0	I	0
Subtotal	24	11	2	11
Physiological				
Weight	4	4 ^b	0	0
Metabolic control	3	2	0	1
Blood pressure	2	2	0	0
Cholesterol	2	2 ^a	0	0
Subtotal	11	10	0	1
Total	57	30	6	21

^aOne study of which reports both control and MI intervention effective for that variable.

power of the study to 61%. (Three studies were pilot studies and therefore do not need to include sample size calculations [1, 3 & 4].)

Procedure and intervention

Reporting of the procedure of interventions were adequately detailed in all studies, however, precise details on the contents of the MI sessions were only given in two of the RCTs [2 & 8] and two of the other four studies [1 & 4]. In one of the RCTs and two of the other studies it was unclear whether MI was delivered as full therapy or brief intervention [4, 6 & 7]. For assessing the amount of MI that patients were exposed to,

327

^bTwo studies of which report both control and MI intervention effective for that variable.

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328 K. M. Knight et al.

the actual length of sessions were reported in only two of the RCTs and one of the other studies [4, 5 & 8].

Three-quarters of the RCTs and other studies included a detailed explanation of the main components and principles of MI, detailing use of reflective listening, rolling with resistance, developing discrepancy, and so on [1, 2, 3, 4, 5 & 8]. Two studies failed to adequately describe the principles of MI [6 & 7], one of which was an RCT and mentioned the use of MI only once in the abstract [7].

Training

Two non-RCT studies described the length and type of training in MI that intervention therapists received, ranging from a combination of workshops, training videos, role play, and individual supervision spread over 3 months, to 15–20 hours of didactic teaching, practice, and reading supervised by a certified trainer [1 & 4].

Only one of the studies, an RCT, made an assessment of the skill level in MI achieved after training, to validate the use of MI in the studies [5] (although two studies did use experienced [3] and certified therapists [8] so assessment of skill level was less of an issue). The assessment used an interview coding tool designed for the study measuring reflecting, exploring, non-judgmental giving of information, advice and patient resistance.

Measures

Given the array of outcomes measured (as highlighted above) it is unsurprising that little homogeneity was found between outcome measures. Most studies measured an average of 7.5 different outcomes, ranging from 4 to 11 with large variation between psychological, life-style change, and physiological outcomes.

Only six of the studies (three of which were RCTs) detailed the use of specific validated measures [1, 2, 4, 6, 7 & 8]. (Details of the different reported validated measures can be obtained by contacting the authors and could not be included within the scope of this review article). Of the 21 different psychological and life-style change outcomes measured overall by all the studies combined, 17 of those were measured with appropriate and validated, standardized instruments. (Only one RCT failed to report use of validated measures for all the outcomes tested in the trial [5]).

Discussion

From the systematic techniques employed in this review to identify articles utilizing MI in a physical health care setting, we identified eight studies in the five domains, diabetes, asthma, hypertension, hyperlipidaemia and heart disease. Only four of eight studies were RCTs, one of which was underpowered, and the other reporting baseline data only. Of the remaining studies, one was a non-random controlled trial, and three were pilot studies.

MI affords high face validity based on the apparent generalizability across domains, ease of transferability to health professionals' existing skills base and the 'common sense' factor it carries in the face of new government guidelines demanding more patient-centred packages of care. Overall, this systematic review has found that the internal content validity of RCTs and other studies in this area remains worryingly low and offers no justification for its current widespread use at this time.

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A systematic review of motivational interviewing in physical health care settings

Effectiveness of interventions

The majority of RCTs and studies found positive results for effects of MI on psychological, physiological, and life-style change outcomes, but the low quality and content validity of studies in this field prevents us from performing meta-analysis and from drawing any firm conclusions about the effectiveness of MI in chronic and physical illness settings at present.

Methodological issues

The main problems with research in this area after rigorous methodological searching of the literature for quality studies include: small sample sizes, lack of power, use of disparate multiple outcomes, need for universal use of validated questionnaires, and poorly-defined therapy and training.

Many studies reporting on the outcome of MI do not provide adequate information on what the intervention involved, or how it may have been modified for the particular target problem or client population, which makes it difficult not only to replicate studies, but also to draw conclusions or make comparisons, as highlighted in a recent review (Britt *et al.*, 2004). Fidelity to intervention is an important concept that is currently difficult to ascertain, as few studies measure or refer to it.

This systematic review supports Rollnick's conclusions that, 'Despite the promise that MI holds for promoting health behaviour change, there are few controlled studies evaluating the efficacy of MI with health problems, with 'clinical innovation remaining ahead of scientific evaluation' (Rollnick, 1996).

Recommendations for health care

This review corroborates the fact that 'the popularity of MI has largely preceded the availability of efficacy data, particularly as its applications have spread beyond the addiction field' (Miller, 2001). In line with the findings of a systematic review recently carried out looking at MI in the field of HIV risk, diet/exercise, and smoking cessation (Dunn *et al.*, 2001) the results from this systematic review have similarly shown that it remains unknown what levels of MI training, MI skill, or MI duration is optimal for interventions in physical health care settings as often these data are not reported, and while the evidence for MI effectiveness remains promising it is not strong enough at present to recommend its dissemination in this area.

Only half of the studies in this systematic review provided adequate evidence of exactly what method was used, and only a quarter explained how practitioners were trained to use MI. Consequently, the methods employed by practitioners may be quite diverse from the true spirit of MI having a critical effect on outcome.

Implications for future research

Taking into account Rollnick's comments in response to Dunn's recent systematic review, and the findings we have discovered through the systematic techniques of this review, there are a number of implications for future research in MI.

There is an urgent need for more rigorous, good quality trials and research to underpin the high face validity that MI carries in domains outside addiction, such as the focus of this review in chronic and physical illness settings.

Many of the design features need attention for the next phase of research. For example, larger sample sizes and power calculations, validated, standardized, and

329

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330 K. M. Knight et al.

generalizable measures, thorough descriptions of the methods used to allow researchers to distinguish between MI as a form of therapy and brief adaptations of the therapy that address behaviour change in different settings, level of training given, and detailed descriptions of the contents of sessions delivered.

Studies striving to include these points in the design of studies will allow for much needed meta-analysis in this area as well as provide researchers with the means to begin assessing factors such as the 'minimum effect dose' of MI, and to investigate research questions such as 'is the reported length of MI intervention related to the observed effect sizes' (Miller, 2001). Similarly, Rollnick argues for the subject of training practitioners to change their behaviour to be afforded the same status in this field as that of client behaviour change (Rollnick, 2001). Britt concludes that further research needs to focus on the process of MI and its key components; for example, what is the best way to structure sessions and which are the optimal methods for responding to resistance (Britt *et al.*, 2004).

Conclusions

The systematic techniques used in this review have revealed that MI does appear to have potential to be an effective intervention in this area, but more and better quality research is desperately needed in this area.

Whilst MI has high face validity, this systematic review has shown that across a number of domains in physical health care settings, the general quality of trials in this area is inadequate and consequently recommendations for its dissemination in this area cannot yet be made. Continued and quality outcome research into MI applied to health behaviour change is urgently required. Issues addressing cost effectiveness to ascertain if MI is more resource intensive than usual care and whether the outcomes achieved by MI balance out resource implications is also needed, as well as further research into the fidelity of trained experienced therapists delivering interventions as intended.

We acknowledge the degree of positive bias introduced into this systematic review by only accepting English language papers, and also the likely publication bias given that many small negative trials are unavailable and unpublished.

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332 K. M. Knight et al.

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