Long-Term Follow-Up of NetmumsHWD: A Feasibility Randomised Controlled Trial of Telephone Supported Online Behavioural Activation for Postnatal Depression at 16 Months Post-Randomisation

Submitted by Kara Marie Bagnall to the University of Exeter as a thesis for the degree of Doctor of Clinical Psychology, May 2014

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Author's Declaration for Joint Working

The empirical paper within this thesis forms one part of a larger body of research. This author, in collaboration with another Trainee Clinical Psychologist, was responsible for collecting the 16-month follow-up data. The design of the trial and original recruitment, intervention, and data collection (at baseline, post-treatment, and 10 month follow-up) had been conducted prior to this author's involvement in the study. The specific research questions and hypotheses related to the relationship between baseline measures and attrition, and to the relationship between adherence and outcome, were this author's own. Data analysis was conducted by this author.

Is it Possible to Prevent Postnatal Depression with Cognitive and/or Behavioural Interventions?

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TARGET JOURNAL: Archives of Women's Mental Health

WORD COUNT: 3,904 (excluding abstract & table contents)

Abstract

Background: Postnatal depression affects a significant proportion of the female population, and has problematic consequences for both the sufferer and her child, as well as for the wider family. Cognitive and behavioural interventions have proven successful in the treatment of postnatal depression, and researchers are increasingly turning their efforts towards preventing the condition with these methods. This review aimed to assess whether interventions with cognitive and/or behavioural components were effective in preventing symptoms or diagnoses of postnatal depression. ***Methods:*** A systematic search of key electronic databases identified studies that assessed the effects of cognitive and/or behavioural interventions in the prevention of postnatal depression. ***Results:*** Nineteen studies were eligible for review. Eight studies described cognitive and/or behavioural interventions that were significantly effective in reducing diagnoses and/or symptoms of postnatal depression. Several pilot studies produced promising but non-significant results, reflecting a lack of power. Bias was present in a number of studies which reduces confidence in these conclusions. ***Limitations:*** Not all studies reviewed explicitly ruled out baseline depression. ***Conclusions:*** Results as to the efficacy of preventative cognitive and/or behavioural interventions for postnatal women are mixed. Both RCTs that involved self-help elements, plus several group interventions, were efficacious at reducing symptoms or diagnoses of depression in postnatal women, and these may be promising avenues for future research. Methodological improvements are required in future research in order to limit bias.

Keywords: postnatal depression, cognitive, behavioural, prevention, intervention

Introduction

Background

Approximately thirteen per cent of women suffer from postnatal depression (N. I. Gavin et al., 2005), with the highest level of risk in the first five weeks postpartum (Cox, Holden, & Sagovsky, 1987). Living with a depressive illness is undoubtedly difficult for the mother, and there are also problematic cognitive, social and emotional implications for the child (Murray et al., 2010), and additional issues related to the impact on partners and families (Burke, 2003). Women who experience postnatal depression are at increased risk of experiencing further episodes of both postnatal and non-postnatal depression (Cooper & Murray, 1995). It is therefore clear that preventing the condition should be of concern to researchers and clinicians alike.

Many postnatal women prefer non-biological interventions to medication-based interventions (Appleby, Warner, Whitton, & Faragher, 1997), in part due to concerns about the contamination of breast milk with antidepressant medication. Fortunately, cognitive behavioural therapy (CBT) has been shown to be an effective treatment for postpartum depression (Cuijpers, Brännmark, & van Straten, 2008). Preliminary results in online behavioural interventions also appear promising (O'Mahen, Richards, et al., 2013; O'Mahen, Woodford, et al., 2013). Given the potential benefits of preventing postnatal depression, researchers are increasingly resorting to trialling preventative interventions based on cognitive and/or behavioural theories, due to their proven evidence base in treating established postnatal depression.

A decade ago, a Cochrane review revealed that psychological and psychosocial treatments for preventing postnatal depression were generally not efficacious (Dennis & Creedy, 2004). However, findings did suggest that

interventions that targeted women at risk, that were individually based, and that were commenced postnatally were more likely to be of benefit. This review has since been criticised for overgeneralisation, and commentators have also pointed out that a relevant study of a successful intervention was not included (Clatworthy, 2012; Matthey, 2005). In contrast, a more recent review found evidence that antenatal interventions aimed at high-risk women during pregnancy could be effective in preventing post-partum depression (Clatworthy, 2012). Nonetheless, this review found evidence that some of the preventative interventions could more appropriately be classed as treatments, as they were offered to women with moderate to severe symptoms of depression. This therefore casts doubt on the conclusion that solely preventative interventions can be efficacious.

In the two years since Clatworthy's (2012) search strategy was undertaken in 2010, several studies involving diverse communities have appeared in the literature. There is some evidence that certain ethnic minorities are at greater risk of postnatal depression, and thus the efficacy of preventative interventions for these groups is of particular interest (A. R. Gavin et al., 2011). Further, since the current search was initiated a new review of preventative interventions has been undertaken suggesting preventative interventions can be efficacious (Sockol, Epperson, & Barber, 2013). However, as with earlier reviews, this also included a number of studies that comprised a majority of women that had probable depression (by virtue of recommended depression scale cut-offs; see, e.g., Cox et al., 1987), thus it confounded prevention with treatment.

The current review therefore aimed to conduct an up-to-date appraisal of the literature on preventative interventions for postnatal depression, in order to

report on their effectiveness in studies in which the majority of women would not be classed as probably depressed, thus classifying the interventions as primarily preventative. It also aimed to incorporate interventions focussing on diverse communities. Due to the evidence base for cognitive behavioural interventions in the treatment of depression, this review focussed solely on interventions that incorporated cognitive and/or behavioural components. Furthermore, given the continued roll-out of cognitive behavioural training as a result of the Improving Access to Psychological Therapies programme in the UK (Department of Health, 2011), the effectiveness of preventative cognitive-behavioural interventions is of widespread relevance to practitioners.

Objectives

This review aimed to report on the efficacy of interventions with cognitive and/or behavioural components in the prevention of diagnoses of, or the reduction in sub-threshold symptoms of, postnatal depression. Guidelines from the Centre for Reviews and Dissemination (2009) were consulted with regard to the design of this review.

Methods

Eligibility Criteria

Studies were eligible for inclusion if they involved: antenatal or postnatal women; a psychological or psycho-educational intervention that included identifiable cognitive and/or behavioural components, including problem-solving components and components from cognitive-behavioural “third wave” therapies; measurement of depressive symptoms or diagnoses as a primary or secondary aim; and measurement of depressive symptoms or diagnoses in the postnatal period. Studies were ineligible if the majority of participants already had a formally diagnosed depressive episode at the outset; if the mean baseline score

for participants was above agreed symptom scale cut-offs for probable depression (unless a depressive episode was formally ruled out; in both cases, studies were included if results for those with and without a (probable) diagnosis were presented separately); if the intervention involved a pharmacological component; if measurement of depressive symptoms or diagnoses was restricted to the antenatal period; and if the paper was written solely in a language other than English. The search was restricted to papers from peer reviewed journals.

Information Sources

Searches were conducted across the following databases:

- Web of Science (1900-present)
- PsycINFO (1806-present)

Search Strategy

The search strategy was as follows:

(Postnatal OR perinatal OR postpartum OR post-natal OR peri-natal OR post-partum OR antenatal OR ante-natal OR prenatal OR pre-natal) AND (prevent* OR cognitive OR behavior* OR behaviour* OR Psychoeducation* OR psycho-education* OR problem-solving) AND depress* AND (therap* OR intervention* OR program* OR counsel* OR treatment*)

The PsychINFO search was limited to peer-reviewed journals in English. The Web of Science search was limited to articles in English.

Study Selection

Titles and abstracts of all results were screened by the author in order to identify possibly eligible studies with reference to the selection criteria. The full version of all possibly eligible studies was accessed and ineligible studies

excluded. Reference lists of previous reviews were also checked for additional studies.

Data Collection Process

A structured data extraction form was developed in Microsoft Excel to enable data exploration. Information from each eligible study was input into the form under relevant headings, covering design; content; means of delivery; profession of facilitator; fidelity of intervention; participant adherence to intervention; duration of intervention; sample size; power; eligibility and exclusion criteria; depression measures; timing of measures; presence of blinding; outcome; presence of intention-to-treat analyses; effect size; type of control group; diversity; attrition; and depression scores at baseline.

Risk of Bias in Individual Studies

Information relating to the presence of power calculations, blinding, randomisation, and intention-to-treat analyses were extracted from the eligible studies to enable critique as to study validity.

Risk of Bias Across Studies

It is possible that publication bias may be present, in terms of non-submission or non-acceptance of non-significant trials for publication. However, investigation of this was beyond the scope of the current review.

Results

Study Selection

Web of Science returned 3,353 results, and PsychINFO returned 1,313 results. The author identified 49 possibly eligible studies from these results based on titles and abstracts. Following the review of the full versions, 19 studies were found to be eligible for inclusion. Figure 1 displays a flow chart of study selection.

Reasons for ineligibility included: studies focussing solely on the antenatal period (e.g., Jesse et al., 2010); “prevention” studies involving women that were diagnosed with depression at baseline (e.g., Cho, Kwon, & Lee, 2008); and a cognitive-behavioural intervention study which was more properly classified as a health visitor training intervention, as the cognitive-behavioural element was delivered to less than one per cent of the sample (Brugha, Morrell, Slade, & Walters, 2011).

Some eligible studies included additional treatment elements for women with high levels of depressive symptomology or diagnosable depression. In these cases, only the preventative elements were addressed in the review, and the treatment elements were not explored.

Study Characteristics

Eleven studies were described as Randomised Controlled Trails (Austin et al., 2008; Chabrol et al., 2002; Hagan, Evans, & Pope, 2004; Howell et al., 2014; Kozinszky et al., 2012; Lara, Navarro, & Navarrete, 2010; Le, Perry, & Stuart, 2011; Mao, Li, Chiu, Chan, & Chen, 2012; Milgrom, Schembri, Ericksen, Ross, & Gemmill, 2011; Tandon, Perry, Mendelson, Kemp, & Leis, 2011), with a further five described as pilot Randomised Controlled Trails (Bernard et al., 2011; Ginsburg et al., 2012; Muñoz et al., 2007; Silverstein et al., 2011; Vieten & Astin, 2008). One study was described as a pretest-posttest, control group quasi-experimental design, although this appeared to be a cluster RCT with only two sites, one randomised to the intervention (Ngai, Chan, & Ip, 2009). A further study was described as a pretest-posttest mutual controlled semi-experimental model (Tezel & Gözüm, 2006), although both randomisation and matching were referred to within the paper. One study was a pilot, non-

randomised controlled trial (Dunn, Hanieh, Roberts, & Powrie, 2012). Table 1 provides a summary of key information from included studies.

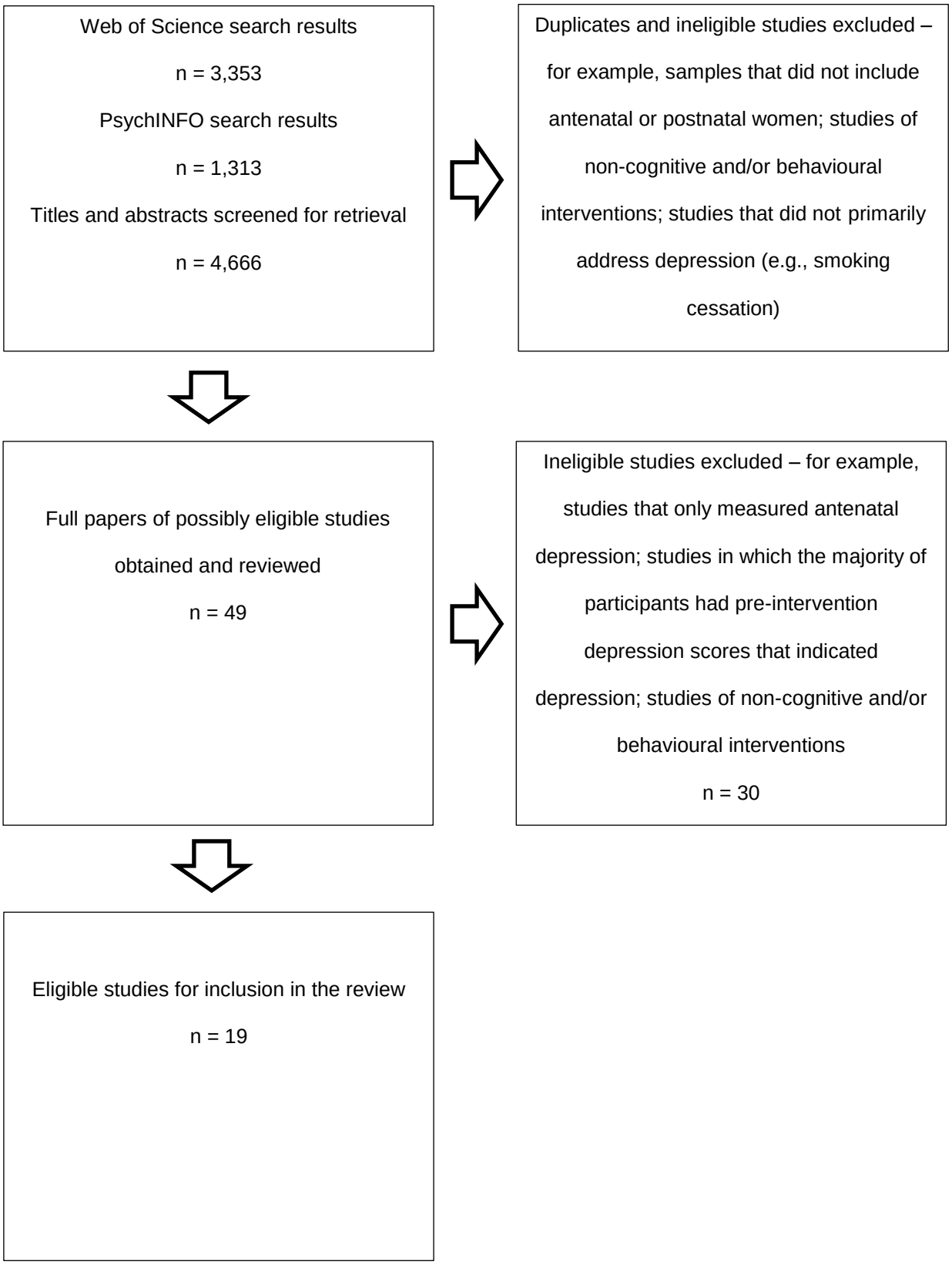

Fig. 1 Flowchart illustrating identification process of included studies

Table 1

Characteristics of Included Studies

Study	Design	Intervention	Duration/Timing	Intervention provider	Depression measure(s)	Timing of outcome measurement	Control
Austin et al. (2008)	RCT	†CBT group	6 wkly 2h AN + 1 booster	Psychologist & midwife	EPDS; MINI	PT, 2mt, 4mt (MINI not post)	Information booklet
Bernard et al. (2011)	Pilot RCT	†CBT & relaxation 1:1	3 x 45–55m PN	Researcher & doctoral student	BDI	1mt post infant discharge	TAU
Brugha et al. (2000)	RCT	†C, PS & social support enhancement group	6 x 2 h wkly AN/PN reunion	Nurses, OTs, & a parent	GHQ-D; EPDS	3mt PN	TAU
Chabrol et al. (2002)	RCT	†*CBT 1:1	1 x 1 h PN	Therapists, including psychology masters students	EPDS; MINI	4-6w PN	TAU
Dunn et al. (2012)	Pilot quasi-experimental trial	MBCT group	8 x wkly AN	MBCT accredited psychiatrist & counsellor	EPDS; DASS - D	PT, 6w PN	Wait-list
Ginsburg et al. (2012)	Pilot RCT	†**CBT 1:1 at home/office	8 wkly 0.5-1h AN & 3 x mtly boosters	American Indian paraprofessionals	CES-D; DISC; EPDS	PT, 4w, 12w, 24w PN	8 x ed support
Hagan et al. (2004)	RCT	†CBT group	6 x 2h wkly PN	Research midwife	SADS	2mt, 6mt, 12mt	Education group
Howell et al. (2014)	RCT	B-ed leaflet & CSM 1:1, plus home-visit	1 x 15m session & 1 x home call 2 wks PN	Masters-trained social worker	EPDS; PHQ-9	3w, 3mt, 6mt	TAU + info on service access
Kozinszky et al. (2012)	RCT	*CB & IPT group	4 x 3h wkly AN	Psychiatrists & health visitors	LQ	2nd trimester, 6-8w PN	TAU including ed
Lara et al. (2010)	RCT	†**CB self-help book, psychoed group, & 2 x 1:1 boosters	8 x 2h wkly AN	n/s	BDI; SCID	6 weeks and 4-6 months PN	TAU + self-help book
Le et al. (2011)	RCT	†**CBT psycho-ed group	8 x 2h wkly AN 3 booster PN	n/s	CES-D	Late AN, 6w, 4mt, 12mt PN	TAU
Mao et al. (2012)	RCT	**CB-based emotional skills management group & 1 x 1:1 counselling	4 x 1.5h wkly + 1 x 1:1 AN	Obstetrician	PHQ-9; SCID	6w PN	TAU = 4 nurse-led sessions

Study	Design	Intervention	Duration/Timing	Intervention provider	Depression measure(s)	Timing of outcome measurement	Control
Milgrom et al. (2011)	RCT	†CB self-help workbook plus telephone support	8 AN modules (+ 1PN) & 8 AN support sessions	Psychologist or trainee psychologist	BDI	12w PN	TAU
Muñoz et al. (2007)	Pilot RCT	†**CB & attachment-based group	12 x wkly AN + 4 booster PN	Postdocs & trainee psychologists	CES-D; EPDS, MMS	PT, 1mt, 3mt, 6mt, 12mt PN	TAU
Ngai et al. (2009)	Cluster RCT	*Learned resourcefulness psycho-ed group	3 x 1h over 2 wks AN	Midwife	EPDS	PT, 6w, 6mt PN	TAU = Routine education
Silverstein et al. (2011)	Pilot RCT	†*PS education 1:1	4 x 25-60m PN	Graduate students	QIDS	Mtly over 6 mt	TAU
Tandon et al. (2011)	RCT	†*CB group	6 x 2h wkly A/PN varied per person	Social worker or psychologist	BDI; MMS	1w PT, 3mt PN	TAU + depression info
Tezel & Gözüm (2006)	Semi-experimental trial	†*PS education 1:1	6 x wkly PN	Nurse researcher	BDI	PT (PN)	6 x wkly nursing care
Vieten & Astin (2008)	Pilot RCT	†MBSR, MBCT & ACT – based group	8 x 2h wkly AN	Psychologist & yoga instructor	CES-D; PANAS-X	PT (AN), 3 mt	Wait-list

Note. RCT, randomised controlled trial; CB(T), cognitive behavioural (therapy); C, cognitive; PS, problem solving; MBCT, mindfulness-based cognitive therapy; B, behavioural; ed, educational; CMS, common-sense model; IPT, interpersonal therapy; MBSR, mindfulness-based stress reduction; wkly, weekly, AN, antenatal; PN, postnatal; h, hour; mtly, monthly; m, minute; OT, occupational therapist; n/s, not specified; EPDS, Edinburgh Postnatal Depression Scale; MINI, mini psychiatric interview; BDI, Beck Depression Inventory; GHQ-D, General Health Questionnaire – Depression subscale; DASS-D, Depression Anxiety and Stress Scale – Depression subscale ; CES-D, Centre for Epidemiologic Studies – Depression Scale; DISC, Diagnostic Interview Schedule for Children; MMS, Maternal Mood Screener; SADS, Schedule for Affective Disorders and Schizophrenia; PHQ-9, Patient Health Questionnaire; LQ, Leverton Questionnaire; SCID, Structured Clinical Interview for DSM-IV; QIDS, Quick Inventory of Depressive Symptoms; PANAS-X, Positive and Negative Affect Schedule – Extended; PT, post-treatment; mt, month; w, week; TAU, treatment as usual. *samples from non-typical populations; **culture-specific adaptation of traditional models indicated in intervention description; † "at-risk" sample or subsample.

Summary of Findings

Five of the RCTs and the cluster RCT found positive outcomes in favour of the preventative interventions. However, five of the RCTs, and the semi-controlled study did not. One quasi-experimental study had encouraging results, but the significance levels were not computed due to the small size of the trial and lack of randomisation (Dunn et al., 2012). None of the five pilot studies found significant intervention effects, although they were probably underpowered to do so; most pilot study authors reported trends in the expected direction and/or small-moderate effect sizes in favour of the intervention, but commented on the need for further work with larger samples.

Mode of delivery. 12 out of the 19 studies involved some form of group intervention. Five of these were successful either at reducing the frequency of probable or actual depression postpartum, or at reducing depressive symptoms postpartum (or both). One intervention was successful only at reducing depressive symptoms during pregnancy, but not postpartum, and one reduced ratings of negative affect during pregnancy only, but not depression. Thus just under half of the group-based interventions had an effect on depression postpartum (excluding the one quasi-experimental pilot trial which did not test for significance). All of the group interventions that were successful were full RCTs, and it may be that the pilot studies were insufficiently powered to obtain an effect – two reported non-significant small effects, for which they were not sufficiently powered. However, four full RCTs of group interventions also failed to find an effect postpartum, and thus the findings on the effectiveness of group interventions are not conclusive.

The sole self-help based intervention with telephone support resulted in significantly lower levels of depression and fewer instances of scores above cut-

off, and this may be a promising avenue for future work (Milgrom et al., 2011). Six studies utilised 1:1 interventions, only one of which found a small but significant intervention effect (Chabrol et al., 2002). However, three were pilot studies; in two of these, trends in the expected direction were reported with small-moderate effects.

There was no obvious link between the number of sessions offered and the effectiveness of the intervention across the studies, with both success and failure of six-session interventions, and yet the success of a single session intervention.

The interventions were delivered by various health professionals and most studies reported that the facilitators had undergone training. There was no obvious link between the profession of the facilitator and the success of the intervention; however, the variability of the professions included means firm conclusions on this topic are not possible. Delivery was carried out by trainee and qualified psychologists; midwives; paraprofessionals; researchers; masters, doctoral and postdoctoral students; occupational therapists; counsellors; social workers; health visitors; obstetricians; and psychiatrists. Only one trial made reference to the accreditation status of facilitators in the field of the intervention (Dunn, Hanieh, Roberts, & Powrie, 2012; both were MBCT accredited).

Content. Eight studies focussed solely on traditional cognitive behavioural interventions, and five of these had non-significant findings (including two pilot studies; the three successful interventions were from full RCTs). Kozinszky et al. (2012) combined cognitive and interpersonal group interventions, and found a small effect. Two small studies piloted mindfulness interventions with cognitive elements; one found a non-significant large effect (Vieten & Astin, 2008), while the other did not calculate effect size (Dunn et al., 2012). One RCT

combined cognitive elements with problem-solving approaches and a focus on social support, but this intervention did not improve outcome over and above the control condition (Brugha et al., 2000). One RCT involved a 15 minute behavioural-educational 1:1 intervention, followed by a home visit to address symptom management, but this was not found to be effective (Howell et al., 2014). On the other hand, a cluster RCT of a “learned resourcefulness” intervention (involving cognitive restructuring, problem-solving, and efficacy enhancement) was significantly better at reducing depressive symptoms than childbirth education alone (Ngai et al., 2009). A pilot study and a semi-experimental study both found no beneficial effect of a problem-solving intervention; the former the latter finding in favour of the nursing-care control; Tezel & Gözüm, 2006). Mao, Li, Chiu, Chan, and Chen's (2012) pilot emotional skills management group proved effective at reducing symptom scores. It is noteworthy that both RCTs that included a cognitive-behavioural self-help book on depression (one telephone-supported; one alongside a group) led to successful outcomes, and this may be a promising line of research in the future (one pilot study did not find this effect).

Participants. The samples for the full CTs ranged in size from 143 to 1488, while the pilot CT samples tended to be smaller, with samples ranging from 9 to 56. The majority of studies targeted women who were classed as “at risk” of postnatal depression, whether through high depression screens, past or family history of depression, or birth complications. Results were mixed, but there appeared to be a slightly greater likelihood of intervention success in studies of women who were not classed as “at risk”.

A number of the studies focussed on delivering interventions to non-typical populations. Specifically, some studies focussed on ethnic minorities or socially

disadvantaged groups, and some were carried out on majority populations in non-Western-European countries. In all, roughly half of the reviewed studies involved non-typical participants, and successful interventions were found for Chinese, Mexican, and Hungarian samples, for a sample of African American women, and for a sample that contained women from diverse socio-economic backgrounds. A number of the studies described the applicability of the chosen intervention to the group, and several made specific cultural adaptations, although sensitive adaptation did not always lead to a successful outcome.

For instance, the intervention for Apache American Indians was developed in consultation with community stakeholders, who believed a cognitive-behavioural approach was consistent with values and practices that were already employed on the reservation as a means to overcome past difficulties (Ginsburg et al., 2012). Furthermore, the training of Apache paraprofessionals in the delivery of the intervention meant that cultural taboos relating to the presence of exaggerated negative thinking could be carefully navigated in work with participants. However, in spite of these adaptations, this intervention fared no better than control. Across all studies, there did not appear to be a link between sensitive adaptation of an intervention and outcome.

Risk of Bias Within Studies

Table 2 summarises study outcomes and relevant bias indicators.

Blinding. Six studies, including three RCTs that showed a significant impact of intervention over control, did not state whether or not outcomes were collected by researchers blind to allocation. The cluster RCT and two group RCTs that found a positive intervention effect were blinded, whereas the remaining four blinded RCTs failed to find a benefit of their intervention over control.

Table 2
Study Outcomes, Effect Sizes, and Evidence of Bias

Study	Outcome	ES statistic [95% CI] (measure; time point)	ITT	Blind	Rand spec	Fidelity ass/rep
Austin et al. (2008)	Similar symptom reduction in INT & CON	n/s	+	+	+	-/-
Bernard et al. (2011)	Trend for lower levels of depression in INT	$f^2 = 0.318$	-	s-r	+	+/+
Brugha et al. (2000)	No sig effect of INT on depression or risk factors	OR = 1.22 [0.63-2.39]	+	+	+	-/-
Chabrol et al. (2002)	Sig greater reductions in frequency of probable depression in INT over CON	OR = 0.46 [0.26-0.81]	+	-	+	+/-
Dunn et al. (2012)	Reliable change analyses in expected direction	n/a	-	s-r	n/a	-/-
Ginsburg et al. (2012)	Similar symptom and rate reduction in INT & CON	*d* = 0.05; 0.22; 0.08; 0.08 (CES-D; PT, 4, 12, 24w) *d* = 0.11; 0.03; 0.22; 0.13 (EPDS: PT, 4, 12, 24w)	-	-	-	+/-
Hagan et al. (2004)	No sig difference on MDD or screening between INT & CON	RR = 1.13 [0.71-1.78]	+	+	+	-/-
Howell et al. (2014)	No sig difference in screens or symptom rates over time between INT & CON	OR = 0.97 [0.59-1.61] (rate)	+	+	+	+/-
Kozinszky et al. (2012)	Small difference in favour INT between those that did not have depression pre-treatment, but did post-treatment	Absolute risk reduction = 0.4%	+	+	+	+/-
Lara et al. (2010)	The cumulative incidence of MDD was sig lower in INT. No symptom effect of INT	n/s	+	n/s	+	+/-
Le et al. (2011)	INT sig reduced symptoms AN but not PN	*d* = -0.28	+	-	+	+/-
Mao et al. (2012)	Symptoms & diagnoses sig lower in INT than CON	OR = 0.29 [0.21-1.01]	+	+	+	-/-
Milgrom et al. (2011)	Sig lower symptom score & fewer above cut-off in INT compared to CON	*d* = 0.6 (symptoms – not ITT)	+	n/s	+	+/-
Muñoz et al. (2007)	No sig difference between INT & CON on symptoms or incidence of MDD	*d* = 0.28 (incidence)	-	n/s	+	+/-
Ngai et al. (2009)	Sig greater reduction in depressive symptoms in INT over CON	n/s	+	+	+	-/-
Silverstein et al. (2011)	Trend towards lower likelihood of episode of moderate-severe depressive symptoms in INT. In sub-threshold subgroup, CON had episode earlier	RR = 0.66 [0.39- 1.11] (symptoms) hazard ratio 0.49 [90.18-1.32] (timing)	+	+	+	+/+
Tandon et al. (2011)	Sig more CON women had symptoms levels above cut-off	$\eta_p 2 = 0.07$	-	n/s	-	+/+
Tezel & Gözüm (2006)	CON sig more effective at reducing symptoms than INT	n/s	-	n/s	-	-/-
Vieten & Astin (2008)	Sig greater decrease in negative affect in INT than CON at PT, but not in depression. Trend in expected direction at follow-up	*d* =0.9 (affect) *d* =0.8 (depression)	-	n/s	-	-/-

Note. INT, intervention; CON, control; sig, significant(ly); MDD, major depressive disorder; AN, antenatal; PN, postnatal; PT, post-treatment; ES, effect size; CI, confidence interval; n/s, not specified; OR, odds ratio; n/a, not applicable; CES-D, Centre for Epidemiologic Studies – Depression Scale; EPDS, Edinburgh Postnatal Depression Scale; RR, relative risk; ITT, intention-to-treat; + = yes; - = no; s-r, paper states measures solely completed by participants in self-reported questionnaires; rand spec, method of randomisation specified in the paper; fidelity ass/rep, type of fidelity assessment stated in paper/outcome of fidelity assessment reported.

Power. Only five studies reported a priori power calculations, the conditions of which were met in the recruitment process. Two were of successful interventions; however, neither six sessions of CBT, nor two sessions of behavioural-educational support, produced an effect over control, despite being adequately powered. On the other hand, a further RCT of an unsuccessful intervention involving cognitive-behavioural, problem-solving and relational elements reported that it was only powered to detect large effect sizes, which may not have been feasible in a prevention study. One of the pilot studies involving a problem-solving intervention conducted a post-hoc power calculation, which confirmed it was underpowered to detect an intervention. No other pilot study reported a power calculation, and seven of the RCTs (two unsuccessful) also failed to report on power.

Randomisation. A variety of randomisation methods were utilised, including computer generated random numbers, allocation based on questionnaire numbers, and coin toss methods. However, two pilot and two full RCTs did not report adequately on randomisation methods.

Intention-to-treat. Twelve of the studies reviewed reported conducting intention-to-treat analyses (including one pilot study), although several also reported completer analyses. Some studies lacked clarity as to which analyses were intention-to-treat and which were not. Usage of intention-to-treat was evenly spread between trials that found promising outcomes and those that did not.

Fidelity. Six studies reported that supervision was used to ensure fidelity of the intervention. Five of the six, plus a further four, utilised some form of observation to assess fidelity, usually through audio or video tape. However,

only three studies stated the outcome of their fidelity measure, which were positive.

Discussion

In contrast to the Cochrane Review (Dennis & Creedy, 2004) on the prevention of postnatal depression, but in line with the most recent review (Sockol et al., 2013), this review has found evidence for the effectiveness of some cognitive and/or behavioural interventions. This was true for some group interventions, and possibly self-help books. Nevertheless, the results were mixed, especially for traditional CBT, while 1:1 interventions performed poorly. The latter is somewhat discrepant to the findings of the earlier Cochrane review, but this is not surprising given the vast majority of studies reviewed in the current paper were not published at that time. Further, the current study reviewed eight interventions not covered by the latest meta-analysis (Sockol et al., 2013). Importantly, the stricter inclusion criteria in relation to pre-intervention depressive symptomology may mean the findings more closely describe the presence of effective preventative, rather than merely treatment, interventions. However, a number of studies had methodological issues that cast doubt on this overall conclusion. For instance, the lack of information on blinding in the RCTs was problematic, as it is subsequently hard to make judgements as to the methodological rigour of these studies. In studies with insufficient blinding, it is possible that researcher bias was present, which may have unfairly favoured the intervention conditions. On the other hand, the lack of fidelity measures and/or reported fidelity outcomes can introduce doubt as to whether the lack of significant findings is due to an ineffective treatment, or simply to poor delivery of an otherwise efficacious intervention. Measurement and reporting on both counts should be improved in future research. However, the majority of studies

reported on randomisation and utilised intention-to-treat analyses, which was encouraging.

It was encouraging to review a large number of studies on minority or non-Western populations, and future research should continue to engage with diversity. It was unfortunate that several sensitively adapted interventions did not prove efficacious. However, in one such study, the control group received a tailored educational intervention, which may have been efficacious in its own right. Comparisons with usual care may therefore be more appropriate in the search for interventions that prevent postnatal depression. On the other hand, this removes the ability to ascertain whether outcomes are due to the specific effects of the intervention or to non-specific effects. Future research should perhaps include measures of process to address this issue.

Limitations

It is possible that this review failed to retrieve all relevant studies. Some included studies did not refer to their intervention as either cognitive or behavioural, and yet the description clearly contained cognitive and/or behavioural elements (such as reframing negative beliefs). It may be that there are more studies that fit this description that fell outside of the search strategy. This would occur if the study did not refer to either *prevention* or to words relating to *cognitive*, *behavioural*, *(psycho-) educational* or *problem-solving* interventions. Future research papers should contain information as to the theoretical bases of all elements of the intervention. This will enable reviewers to more effectively search the relevant literature relating to specific interventions.

In studies designed to prevent depression, it is important that existing depression is ruled out at baseline. This practice did not always occur in the

studies reviewed in this paper, and it means caution should be taken in interpreting the findings of this review. Where depression was not ruled out, it may be that the intervention was serving to treat existing depression, rather than to prevent a hypothetical future episode, and this tells the reader very little about prevention. Further, whilst the majority of participants from included articles fell below cut-offs, a minority did not, and it is possible that positive effects were the result of effective treatments for this minority, rather than preventative interventions for the majority. Therefore, whilst this review found evidence to suggest that cognitive and/or behavioural interventions could lead to lower levels of depressive symptomology in the postpartum period, this may merely be the result of effective treatment for antenatal depression prior to the commencement of the postnatal period, rather than prevention of a depressive episode per se. Thus the terminology around prevention can appear somewhat misleading. Future researchers studying the prevention of postnatal depression should endeavour to rule out depression at baseline using established methods for the diagnosis of depression; alternatively, they should present data for depressed and non-depressed participants separately.

The inclusion criteria for studies in this review utilised cut-offs recommended for English language-speaking participants. However, many of the reviewed studies involved non-English-speaking women, and thus these cut-offs may not adequately apply to these groups. Thus there is a chance this review may have included studies where the majority of non-English-speaking-women would have been classed as probably depressed under local criteria, falling foul of the inclusion criteria. However, the opposite may also be true, with the potential for studies to have been incorrectly excluded based on English-speaking criteria (e.g., Cho et al., 2008). It is difficult to assess which possibility

is correct, as authors often failed to state the cut-offs of the local-language version of the scale they were using, or to reference the local-language scale (instead referencing the English-language version even when a local-language version was utilised). It would therefore be helpful for future researchers to correctly describe and reference the local-language versions of the scales they have utilised.

Finally, this review did not utilise statistical analyses to address the review question, and as such conclusions are merely tentative. The next logical step would be to conduct an updated meta-analysis, taking into account the more stringent inclusion criteria in relation to pre-intervention depression.

Conclusions

Results as to the efficacy of preventative cognitive and/or behavioural interventions for postnatal women are mixed. Many of the group interventions reviewed were effective, but several were not, and 1:1 interventions performed poorly. The full RCTs involving supported self-help were both efficacious at reducing symptoms and diagnoses of depression in postnatal women, and this may be a promising avenue for future research. Furthermore, the extension of pilot research may mean new conclusions are reached in future reviews. Future studies should incorporate and report on measures designed to improve methodological rigour, including blinding, randomisation procedures, power calculations, and intention-to-treat analyses. They should also endeavour to exclude baseline depression when measuring preventative effects.

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Appendix

Copy of Instructions to Authors from Archives of Women's Mental Health

Original Contributions/Research Articles

Original Contributions/Research Articles should be arranged under the following headings:

Abstract. Not to exceed 150–200 words.

Keywords. Not more than five.

Introduction. To include the background literature as well as the objective(s) of the study.

Materials and methods. Describe the basic study design. State the setting (e.g., primary care, referral centre). Explain selection of study subjects and state the system of diagnostic criteria used. Describe any interventions and include their duration and method of administration. Indicate the main outcome measure(s). Specify the dates in which data were collected (month/year to month/year).

Results. Include the key findings. Give specific data and their statistical significance, if possible (include p value if findings were significant). Subset Ns should accompany percentages if the total N is ‹100.

Discussion and Conclusion. Sections conform to standard scientific reporting style.

Reviews

Reviews are intended to draw together important information from recent publications on subjects of broad interest. They are meant to provide a venue for critical examination and considered opinion of such information.

Reviews are not meant to be encyclopaedic and should not exceed 20 pages when typed. Reviews may contain figures and tables. References should be cited in the same way as in full-length articles.

It is recommended that authors contact the Editor-in-Chief beforehand to determine if a proposed review is likely to be suitable for publication. Reviews should be comprehensive, fully referenced expositions of subjects of general interest, including background information and detailed critical analyses of current work in the field and its significance. They should be designed to serve as source materials.

Title Page

Abstract. Please provide a structured abstract of 150 to 250 words which should be divided into the following sections:

- Purpose (stating the main purposes and research question)
- Methods
- Results
- Conclusions

Keywords. Please provide 4 to 6 keywords which can be used for indexing purposes.

Text

Text Formatting.

- Manuscripts should be submitted in Word.
- Use a normal, plain font (e.g., 10-point Times Roman) for text.
- Use italics for emphasis.
- Use the automatic page numbering function to number the pages.
- Do not use field functions.
- Use tab stops or other commands for indents, not the space bar.
- Use the table function, not spreadsheets, to make tables.
- Use the equation editor or MathType for equations.

Headings. Please use no more than three levels of displayed headings.

Abbreviations. Abbreviations should be defined at first mention and used consistently thereafter.

Footnotes. Footnotes can be used to give additional information, which may include the citation of a reference included in the reference list. They should not consist solely of a reference citation, and they should never include the bibliographic details of a reference. They should also not contain any figures or tables. Footnotes to the text are numbered consecutively; those to tables should be indicated by superscript lower-case letters (or asterisks for significance values and other statistical data). Footnotes to the title or the authors of the article are not given reference symbols. Always use footnotes instead of endnotes.

Acknowledgments. Acknowledgments of people, grants, funds, etc. should be placed in a separate section before the reference list. The names of funding organizations should be written in full.

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Tables.

- All tables are to be numbered using Arabic numerals.
- Tables should always be cited in text in consecutive numerical order.
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Figure Lettering.

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- Avoid effects such as shading, outline letters, etc.
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Figure Numbering.

- All figures are to be numbered using Arabic numerals.
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Integrity of Research and Reporting

Ethical standards. Manuscripts submitted for publication must contain a statement to the effect that all human and animal studies have been approved by the appropriate ethics committee and have therefore been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments.

It should also be stated clearly in the text that all persons gave their informed consent prior to their inclusion in the study. Details that might disclose the identity of the subjects under study should be omitted.

These statements should be added in a separate section before the reference list. If these statements are not applicable, authors should state: The manuscript does not contain clinical studies or patient data. The editors reserve the right to reject manuscripts that do not comply with the above-mentioned requirements. The author will be held responsible for false statements or failure to fulfil the above-mentioned requirements.

Conflict of interest. Authors must indicate whether or not they have a financial relationship with the organization that sponsored the research. This note should be added in a separate section before the reference list.

If no conflict exists, authors should state: The authors declare that they have no conflict of interest.

Long-Term Follow-Up of NetmumsHWD: A Feasibility Randomised Controlled Trial of Telephone Supported Online Behavioural Activation for Postnatal Depression at 16 Months Post-Randomisation

SUPERVISOR: Heather O'Mahen

TARGET JOURNAL: Archives of Women's Mental Health

THIS WORK HAS BEEN SUBMITTED IN PARTIAL FULFILMENT OF REQUIREMENTS FOR THE DOCTORATE IN CLINICAL PSYCHOLOGY DEGREE

WORD COUNT: 7,646 (excluding table contents)

Abstract

Purpose: Postnatal depression has significant negative outcomes for both mother and baby. Cognitive-behavioural interventions have proven promising in its treatment, but there are a number of barriers, specific to the postnatal period, which lead to low take-up of treatment. Online interventions may circumvent some of these barriers. However, evidence of long-term follow-up is sparse, in spite of the importance of knowing how such treatments work over the longer-term. ***Methods:*** Long-term follow-up of postnatal women participating in a feasibility randomised controlled trial of NetmumsHWD, an online behavioural activation treatment with telephone support. ***Results:*** Retention rates of over 70 percent were obtained. There were small but non-significant effects of treatment on depressive symptomology and behavioural activation scores at 16 months post-randomisation. Baseline depression and behavioural activation scores predicted attrition prior to the implementation of outreach strategies for data collection; these systematic differences in attrition disappeared post-implementation. Measures of treatment adherence were not related to outcome. ***Conclusions:*** Collection of long-term follow-up data from postnatal women appears feasible. The findings demonstrate the importance of outreach in maximising retention, especially in relation to the generalizability of results. Future research should consider ways to assess treatment engagement and its relationship with outcome.

Keywords: postnatal depression, behavioural activation, attrition, adherence, long-term follow-up

Introduction

Postnatal Depression and Treatment Access

Approximately 13 percent of women will suffer from postnatal depression (Gavin et al., 2005). In addition to the impact of depression on the mother, there are also negative, longitudinal effects on the cognitive, social and emotional development of the infant (Murray et al., 2010), as well as on the wellbeing of partners and families (Burke, 2003). Despite these difficulties, help-seeking amongst women with postnatal depression is low (Buist et al., 2005). This may, in part, be attributable to the unique barriers of the postnatal period that make participation in traditional office-based treatments difficult (O'Mahen & Flynn, 2008). Transportation and childcare are cited as particular issues for new mothers (Goodman, 2009), as well as the stigma associated with developing depression after the birth of a child, and the impact this can have on perceptions of being a "good mother" (Shakespeare, Blake, & Garcia, 2003). These issues mean depressed new mothers often put off seeking help. It has been hypothesised that the provision of online interventions may circumvent some of these barriers (Kohn, Saxena, Levav, & Saraceno, 2004).

The Netmums Helping With Depression (NetmumsHWD) course was designed and piloted as a new online behavioural activation treatment for postnatal depression (O'Mahen, Richards, et al., 2013). Whilst the effectiveness of both standard cognitive behavioural therapy (CBT) and its online counterpart (eCBT) have been demonstrated in a number of randomised controlled trials in the treatment of depression (see, e.g., Cuijpers, Brännmark, & van Straten, 2008; Christensen, Griffiths, & Jorm, 2004; Warmerdam, van Straten, Twisk, Riper, & Cuijpers, 2008), pilot qualitative studies suggested a need for a more individualised treatment for women with postnatal depression (O'Mahen et al.,

2012). Examples of individualised components for the postnatal period not found in standard depression treatment manuals include consideration of the mother-infant relationship, attention to sleep in the postnatal period, and management of transition and identity change as a result of a new baby. Behavioural activation, which has been found in at least one randomised controlled trial (RCT) to be as effective as CBT (Jacobson, Martell, & Dimidjian, 2001), was selected as the treatment. It is straightforward and easy to understand, and may therefore be particularly suitable for postnatal mothers, who may struggle with the time constraints associated with raising an infant. To ensure the behavioural activation treatment met the specific needs of postnatal mothers, it was adapted to include postnatal components related to the particular issues of the postnatal period (see O'Mahen, Richards, et al., 2013 for further detail).

Feasibility of Long-Term Follow-Up

Post-treatment and six-month follow-up data for the primary outcome of NetmumsHWD have been reported elsewhere (see O'Mahen, Richards, et al., 2013). However, the most recent Cochrane review on the topic of postnatal depression criticised the lack of information on the long-term effectiveness of psychological interventions in the treatment of postnatal depression, which precluded follow-up analyses (Dennis & Hodnett, 2007), a problem also found in the most recent meta-analysis to date (see Sockol, Epperson, & Barber, 2011). Given the negative impact of postnatal depression on mother and baby, it is critical to know how treatments for postnatal depression function over the longer-term. It is particularly important to assess whether the positive effects of treatment seen in the short-term remain during the longer-term, once treatment has been discontinued. The primary aim of the current study was therefore to

investigate the feasibility of long-term follow-up in the NetmumsHWD Phase II trial, in accord with the UK Medical Research Council framework for complex interventions (Craig et al., 2008), with the aim of informing a Phase III RCT. The study was therefore designed to assess retention rates, to enable estimation of effect sizes, to examine the relationship between adherence and outcome, and to enable investigation of predictors of attrition. The rationales for each aim are discussed in detail in the following sections. This research thus acts as a starting point from which to address the dearth of research into longer-term outcomes for postnatal depression, particularly amongst research into more accessible, internet-based treatments.

Retention. Compared to unsupported, open-access treatment, attrition rates in the telephone-supported pilot study of NetmumsHWD were much lower (62 percent versus 14 percent; O'Mahen, Woodford, et al., 2013; O'Mahen, Richards, et al., 2013). However, it is important to assess attrition rates over longer-term follow-up. Previous follow-up research into internet-based treatment for depression has proven feasible, although rates of attrition at 12 month follow-up were as high as 40 percent (Mackinnon, Griffiths, & Christensen, 2008). However, there are a number of factors related to the postnatal period that suggest it may be particularly difficult to obtain long-term follow-up data from postnatal women. For instance, the majority of women in the United Kingdom return to work within the first year of childbirth (Gregg, Washbrook, Propper, & Burgess, 2005). Assuming a similar return to work rate in the present sample, this change in circumstance may mean women have less time on their hands to engage in research 16 months post-randomisation. A return to work would also narrow the time during which researchers could contact women, further increasing the likelihood of participants being lost to follow-up.

Furthermore, the length of the follow-up period means there is a possibility of a second pregnancy and childbirth for participants, and thus the time-intensive nature of a second new baby may also reduce the likelihood of follow-up participation. To increase the likelihood of longer-term retention an outreach approach to data collection was planned, involving telephone, text, and email follow-up, in line with recommendations for longitudinal research (Sullivan, Rumptz, Campbell, Eby, & Davidson II, 1996).

The primary research question was thus:

(i) Is it feasible to collect 16 month post-randomisation outcome data from postnatal women in a supported internet-based intervention trial of NetmumsHWD for the treatment of postnatal depression?

Given the findings of previous internet-based research, alongside the improvements in retention seen with the addition of telephone support to NetmumsHWD, and the planned outreach approach, it was hypothesised that collection of 16 month follow-up data in a supported internet-based intervention trial of NetmumsHWD would be feasible in terms of participant retention. In line with the higher end of the attrition rates found in previous internet-based research, given the additional challenges of the postnatal period, an attrition rate of approximately 40 percent or below was deemed acceptable.

Treatment effects. In order to inform sample size calculations for a Phase III trial, this study aimed to estimate treatment effect sizes (and 95% confidence intervals). The second research question was thus:

(ii) What are the estimated effect sizes for the follow-up outcomes of NetmumsHWD?

It was hypothesised that the long-term follow-up estimates would reveal a small-medium effect size, in line with comparable supported internet-based

interventions (see, e.g., Andrews, Cuijpers, Craske, McEvoy, & Titov, 2010).

Adherence and outcome. Predictors of adherence to the NetmumsHWD treatment protocol have been reported elsewhere (see O'Mahen, Richards, et al., 2013). The current study aimed to extend this research by investigating whether adherence to NetmumsHWD is a predictor of outcome. A better understanding of the relationship between adherence and outcome might enable researchers to better inform participants in a Phase III trial about level of input required, thus improving informed consent procedures. It might also inform research into ways of ensuring treatment adherence. A systematic review of internet-based treatments found that the number of modules completed by participants is positively associated with good outcome in studies of depression, but that time spent logged on is not (Donkin et al., 2011). It was therefore expected that number of modules completed would be associated with improved treatment outcome in NetmumsHWD.

Our third research question was thus:

(iii) Are number of modules completed and sessions attended (but not number of modules started) positively related to EPDS outcome at 17 week, 10 month and 16 month follow-up?

Attrition

The predicted high rates of attrition akin to those found in internet trials and in studies of depressed populations are far from ideal. Longitudinal designs create the possibility that different types of people might be systematically excluded over time (Hollon, Shelton, & Loosen, 1991). Thus attrition can bias a data set, result in the loss of statistical power, and reduce the internal and external validity of a study's findings (Bender, Iklé, DuHamel, & Tinkelman, 1997).Yet it is essential to know how more accessible, internet-based

treatments for postnatal depression, such as NetmumsHWD, function over the long-term, and it is therefore critical to identify systematic attrition so that high-risk groups can be identified in future trials. Importantly, a better understanding of predictors of attrition could contribute to the development of enhanced trial procedures around recruitment and retention of high-risk groups, thereby ensuring samples and results are more representative (Zebracki et al., 2003). This research could therefore provide a starting point for the development of interventions aimed at preventing dropout in standard internet-based treatments for postnatal depression. The following sections consider possible theoretical bases for variability in attrition on which the research hypotheses are based.

Depression, behavioural activation, and attrition. According to behavioural theories of depression, behavioural symptoms of depression (characterised by inactivity and avoidance, etc.) are conceptualised as coping strategies designed to help an individual avoid environments that provide either low levels of positive reinforcement, or high levels of aversive control (Jacobson et al., 2001). Indeed, even within cognitive-behavioural theories, the vicious cycle of decreased interest in activity and the associated reduction in activity is hypothesised to be a key feature of depression (Garland, Fox, & Williams, 2002) by virtue of the lack of positive reinforcement associated with inactivity. These behavioural patterns are hypothesised to be strengthened by cognitions that prioritise essential tasks at the expense of other, less essential (but potentially beneficial) tasks (Garland et al., 2002). Purely cognitive theories, on the other hand, maintain that the triad of negative biases about the self, the world, and the future (the latter related to hopelessness) may be responsible for the maintenance of the observed inactivity (Beck, 1963; for a review of supporting evidence, see Haaga, Dyck, & Ernst, 1991). Either way, the effect on

activity is similar. Furthermore, potential neurobiological mechanisms for the decreased motivation seen in depressed individuals have also been proposed (for a review, see Nestler et al., 2002), and impaired concentration remains a key feature of depression (American Psychiatric Association, 2013). Thus depressed individuals, whether through behavioural, cognitive, and/or biological mechanisms (or more likely a mixture of the three), are generally more likely to display decreased activity levels compared with non-depressed individuals. It's not unreasonable to assume this behaviour would generalise to trial participation. In addition to avoidance patterns, routine disruptions are also hypothesised to be a component of depressive disorders (Jacobson et al., 2001; Ehlers, Frank, & Kupfer, 1988). Indeed, the disruption of routine brought about by a new baby may exacerbate depressive symptoms further, worsening the behavioural symptoms of depression, and further decreasing the likelihood of trial participation.

Taken together, the research suggests it would be reasonable to anticipate that individuals with higher levels of depressive symptomology (and, correspondingly, lower levels of behavioural activation) would be less motivated to remain in the NetmumsHWD research programme and thus more likely to drop out. Indeed, in epidemiological research, higher depressive symptom severity has been found to be positively associated with attrition (Lamers et al., 2012). Furthermore, higher depression symptomology has been found to be associated with attrition in both reminder-supported and unsupported online interventions for depressed individuals (Clarke et al., 2002; Clarke et al, 2005; Mackinnon et al., 2008; the latter only in the control group). A study of behavioural activation for depressed cancer patients found a similar pattern (Hopko, Robertson, & Colman, 2009), as did a study of chronically depressed

individuals undergoing maintenance treatment (Monroe, Roberts, Kupfer, & Frank, 1996). However, depression severity does not always predict attrition (see, e.g., Westra, Dozois, & Boardman, 2002). It may be that, sometimes, individuals with higher levels of depression are more desperate for treatment, and are able to counter their reduced motivation when activity is treatment-oriented; or, it may be that the nature of some trials are either less aversive or more enabling than others. Given these discrepancies, combined with the greater needs of women with higher levels of depressive symptomology (and thus the importance that research includes their data), it is important to investigate the illness-related predictors of trial attrition in mothers with postnatal depression, in particular in relation to the generalizability of the current trial.

Furthermore, given the intervention is designed to treat depression, it may be that by the follow-up phase, assuming the intervention is effective, baseline depression no longer has an impact on attrition. Thus one might expect prediction of attrition post-treatment, but not at 10 month or 16 month follow-up, and it is thus important to investigate all time points.

Social and financial resources and attrition. Research has shown that single mothers (defined as mothers who are not in a relationship) are more likely to experience episodes of depression, more likely to report higher levels of chronic stress, more likely to have experienced more recent life events, and more likely to report a greater degree of childhood adversity compared with married mothers (Cairney, Boyle, Offord, & Racine, 2003). Thus it is important that suitable treatments are found for single mothers, and that researchers are aware of, and can act to mitigate, potential differential attrition. Marital status was not found to predict treatment attrition in a study of behavioural activation

for depressed cancer patients (Hopko et al., 2009). However, this study contained no follow-up, and there are a number of factors associated with the postnatal period that may mean relationship status could have a differential effect on attrition in postnatal women.

Parenting is a time consuming task, and research suggests that, while single mothers spend similar amounts of time with their children to mothers in a two-parent family, single mothers subsequently spend less time on other things, such as household tasks (Sanik & Mauldin, 1986). Furthermore, there is evidence to suggest that both adequate prenatal and general healthcare utilisation among single mothers is lower than in two-parent families (Feijen-de Jong et al., 2012; Westin & Westerling, 2006). Single mothers are also more likely to report lower levels of perceived social support, social involvement, and frequency of contact with friends and family than married mothers (Cairney et al., 2003), thus there is little opportunity for non-couple relationships to mitigate the effects of being single on usage of time and healthcare. Taken together, it may be that single mothers have less time on their hands, and less support, to engage in treatment and/or research-related activity compared with mothers in a relationship, and thus one might expect relationship status to be associated with trial attrition.

However, lack of perceived social support more broadly, rather than single relationship status per se, is also of relevance. Mothers with low levels of perceived social support tend to report poorer health during pregnancy, to book in for prenatal care at a later point, and to report higher levels of postnatal depression than those with good social support (Webster, Linnane, & Dibley, 2000). It is therefore essential to investigate the effects of perceived availability of, and access to, both practical and emotional social support on trial attrition in

order to inform retention strategies for mothers with low levels of perceived social support in future trials. By definition, one might expect women who have lower levels of perceived social support to have less support to accomplish a range of tasks, including therapy. Further, the lack of support in completing day-to-day tasks may mean mothers have little time to engage in non-essential tasks, such as therapy and trial participation. Thus one might predict that women with low levels of perceived social support to be more likely to drop out of the NetmumsHWD trial.

On both counts, these predictions are likely to be especially true at long-term follow-up, at a time when single mothers, or those lacking in social support, may no longer be in receipt of maternity benefits, and may therefore have the remainder of their (already limited) time taken up by work commitments. In support of this idea, research has shown that the single mothers who spend least time on household tasks are those that are also employed (Sanik & Mauldin, 1986).

Low-income women are at an increased risk of depression (Lorant et al., 2003), and yet they may also have less access to specialised mental health services (Alegría, Bijl, Lin, Walters, & Kessler, 2000). Low-income women have reported a myriad of additional difficulties when interviewed, including problems accessing food and shelter, the need to work multiple jobs or to survive on benefits, social isolation, and the experience of high rates of crime (Boyd, Diamond, & Bourjolly, 2006). Thus, whilst low-income women have a particular need for mental healthcare, they also have a range of practical and time-consuming difficulties to contend with, which may mean appropriate utilisation of, and adherence to, healthcare is limited. Indeed, low income has been found to predict attrition even in medication-based treatments for depression, which

require less of an input from the client than therapy-based treatments (Warden et al., 2009). This may be because time is taken up by more practical issues, and, furthermore, especially once treatment is over, follow-up participation may be a very long way down the list of priorities for low-income women. Thus one might expect trial attrition for low-income mothers in NetmumsHWD to be high. On the other hand, a recent review of treatment for depression in low-income women found that efforts by researchers to overcome practical treatment barriers has led to better treatment engagement and retention (Levy & O'Hara, 2010). It is therefore possible that the internet-based delivery of the current trial, along with its outreach approach to data collection, will go some way towards minimising the potential impact of low household income on trial attrition.

The fourth and final research question was thus:

(iv) Do psychological and/or demographic factors predict attrition from an internet-based treatment for postnatal depression at 17 weeks, 10 months, and 16 months post-randomisation?

In line with previous research, it was hypothesised that high depressive symptomology, low behavioural activation, low perceived social support, low household income, and single relationship status would predict attrition.

Methods

Design

This study describes the follow-up of participants in a single-blind Phase II (feasibility) randomised controlled trial of supported NetmumsHWD versus treatment as usual (TAU).

Conditions. ***NetmumsHWD (intervention).*** The intervention was based on Addis and Martell's (2004) manual for behavioural activation. It was adapted for the postnatal period by O'Mahen et al. (2012) in collaboration with the

Netmums parenting website and a Lived Experience Steering Committee Group comprised of three women who had previously experienced postnatal depression. The NetmumsHWD intervention consisted of five core behavioural activation modules plus two optional modules and an additional relapse prevention module. The modules were designed to help users develop an understanding of the links between their mood and their activity levels. Building on this understanding, users were then assisted to develop a plan to reduce their unhelpful avoidance and related behaviours, and to simultaneously increase more meaningful behavioural activation.

The support element was provided by qualified psychological wellbeing practitioners (PWPs) in the form of 12 telephone support sessions over a 17 week period, allowing for missed and rescheduled appointments. The initial session lasted for no longer than 50 minutes, with subsequent sessions lasting between 20 and 30 minutes each. All PWPs received five days of training on the specifics of NetmumsHWD, and were provided with weekly supervision throughout the supported element of the trial.

Participants in the treatment arm also had access to an online forum supported variously by a health visitor, a telephone supporter, a parent supporter, or a clinical psychologist.

Treatment as usual (TAU; control). Participants in TAU were able to access ongoing treatment through their GP, health visitor, or other healthcare provider. Women in TAU also had access to the publically accessible Netmums.com online postnatal depression chat room, which is supported by trained parent supporters who are supervised by specialist health visitors. There were no restrictions placed on the kind of usual treatment received. Usual treatment usage was monitored post-treatment.

Sample and Participants

Participants were recruited via the UK-based Netmums parenting website. The study was advertised through the Netmums Facebook page, the Netmums Twitter account, their internet newsletter, and on online banners placed on the Netmums website. Interested parties were directed to a website containing participant information, consent forms, and eligibility assessment forms. This method of recruitment was selected based on research which found that standard internet methods of advertising were the most adequate for recruitment in internet-based trials (Woodford, Farrand, Bessant, & Williams, 2011). Inclusion criteria required that participants were aged 18 or over, had a live baby born within the past 12 months, had an EPDS score greater than 12, and had diagnosable major depression as determined by the Clinical Interview Schedule-Revised (CIS-R; Lewis, Pelosi, Araya, & Dunn, 1992). Participants were excluded if they had a psychotic disorder, a bipolar disorder, and/or current substance or alcohol abuse issues. They were also excluded if they had active suicidal ideation, or if they were receiving formal psychotherapy. However, participants were still included if on antidepressant medication. Participants with impairments that would make internet usage or telephone support impractical, such as visual, reading or hearing difficulties, were also excluded. Further details on the design, recruitment strategy, and participant make-up can be found in O'Mahen, Richards, et al. (2013).

Justification of sample size. As this was a feasibility study, Browne's (1995) recommendation to have at least 30 participants in each arm of a pilot study was followed. This number was inflated slightly to allow for the anticipated drop-out associated with supported, internet-based interventions. A total of 83 participants were subsequently randomised to the study.

Randomisation

Eligible participants were randomised to either the intervention or TAU arm by an automated computer system, which was triggered by a participant clicking on the relevant link in an initial study email. Randomisation was stratified by usage or otherwise of antidepressant medication. Researchers were blind to treatment condition.

Measures

Depression. The Edinburgh Postnatal Depression Scale (EPDS; Cox, Holden, & Sagovsky, 1987) was used to measure depressive symptomology. It is a 10-item self-report scale with satisfactory reliability and validity, which is sensitive to change in depressive severity over time (Cox et al., 1987). Participants are shown a statement (e.g., “I have been able to laugh and see the funny side of things”) and asked to select which of four responses comes closest to how they have been feeling during the past seven days (e.g., “As much as I always could;” “Not quite so much now;” “Definitely not so much now;” or “Not at all”). Responses are scored zero, one, two, or three, and responses from all ten items are summed to give the total score. A cut-off of 12 or 13 is usually indicative of depression (Cox et al., 1987).

Anxiety. The Generalized Anxiety Disorder Scale (GAD-7; Spitzer, Kroenke, Williams, & Löwe, 2006) was used to measure symptoms of anxiety. It is a seven-item self-report scale that has good reliability and validity (Löwe et al., 2008). Participants are shown a list of problems (e.g., “Feeling nervous, anxious or on edge”) and asked to rate the frequency of the problems over the past seven days on a four-point scale (zero = “Not at all;” one = “Several days;” two = “More than half the days;” and three = “Nearly every day”). Scores are summed, and cut-off points of five, ten, and 15 are indicative of mild, moderate

and severe anxiety respectively (Spitzer et al., 2006).

Behavioural activation. The Behavioral Activation for Depression Scale (BADS; Kanter, Mulick, Busch, Berlin, & Martell, 2006) was used to measure levels of behavioural activation and avoidance. It is a 25-item self-report scale with good psychometric properties, including construct validity (Kanter, Rusch, Busch, & Sedivy, 2008). The items cover four key areas: Activation, Avoidance/Rumination, Work/School Impairment, and Social Impairment. Participants are shown a series of statements (e.g., "I stayed in bed for too long even though I had things to do") and asked to indicate on a seven-point scale, from zero ("Not at all") to six ("Completely"), how much each statement was true for them during the past seven days, the present day included. Items are reversed-scored where necessary, and then the total score is summed. Higher scores indicate higher levels of behavioural activation.

Functional impairment. The Work and Social Adjustment Scale (WSAS) was used to measure the impact of an individual's difficulties across various work and social domains (Mundt, Marks, Shear, & Greist, 2002). It is a reliable and valid five-item self-report scale, sensitive to treatment-related change (Mundt et al., 2002). Participants are asked to rate the impact of their problems on a nine-point scale, from zero ("Not at all impaired") to eight ("Very severely impaired") across five domains: work, home management, social leisure activities, private leisure activities, and ability to form and maintain close relationships with others. Under the work domain participants are able to select "Not applicable," and thus mean scores were calculated for the purposes of the current study. Higher scores indicate greater levels of impairment.

Perceived social support. The Social Provisions Scale was used to measure participants' perceptions of social support across six domains: reliable

alliance; attachment; guidance; nurturance; social integration; and reassurance of worth (Cutrona & Russell, 1987). Research has supported the reliability, validity, and factor structure of the measure (Cutrona & Russell, 1987). Participants are asked to think about their current relationships with friends, family members, co-workers, and community members, etc., whilst reviewing a set of statements (e.g., “There are people I can depend on to help me if I really need it”). They are then asked to rate the extent to which they agree that each statement describes their current relationship with other people on a four-point scale, from zero (“Strongly disagree”) to four (“Strongly agree”). Necessary items are reversed-scored, and the total score summed to provide a global social support score. Higher scores represent perceptions of greater social support.

NetmumsHWD adherence. Adherence was measured using three markers: (i) the number of modules started (but not completed); (ii) the number of modules completed; and (iii) the number of telephone therapy sessions completed.

Socio-demographic variables. Data on household income and relationship status were collected at baseline.

Procedure

Baseline and demographic data were input online by participants as part of study sign-up. Once treatment had been completed (17 weeks post-randomisation), emails asking participants to complete their 17 week, 10 month, and 16 month post-randomisation measures were sent out automatically by the computer system. Each email contained a link to the study webpages where participants were asked to log in and complete the required measures (the EPDS, the GAD-7, the BADS, the WSAS, and the SPS, plus additional

measures not the focus of the current study). The computer programme saved their responses in the system. The programme automatically sent out three reminder emails to those who failed to respond to the first email (at five, seven and 10 days after the initial email). An outreach strategy was initiated if participants failed to respond to the automated emails. This consisted of researchers making personal contact via email, telephone, and/or text message in order to collect the remaining data. Outreach was therefore designed to be flexible, and was thus open to requests from participants in terms of appropriate timings for data collection, which included provision during evenings and weekends. Data were collected between September 2011 and September 2013.

Data Analysis Strategy

Effect size estimation. Cohen's *d* was calculated for outcomes on the EPDS, the GAD-7, the WSAS, and the BADS using an Excel-based calculator (accessed from www.cem.org/evidence-based-education/effect-size-calculator). Confidence intervals were calculated using the same software. The odds ratio was calculated for the effect of intervention on outcome in terms of probable depression (a score of 13 or more on the EPDS).

Means and standard deviations for these calculations (and all others) were analysed using IBM SPSS version 21 (IBM, USA).

Predictors of attrition. One-way ANOVAs were used to examine the relationships between attrition (defined as non-completion of the EPDS) and baseline depression, baseline behavioural activation, baseline perceived social support, and baseline household income. A chi-square test was used to examine the relationship between attrition and baseline relationship status (being in a relationship was defined as being married, having a live-in partner,

or having a live-out partner). Separate calculations were made for each time-point (17 weeks, 10 months, and 16 months post-randomisation). The same strategy was also used to analyse the relationships between pre-outreach attrition (defined as non-completion of the EPDS after all three automatic reminder emails had gone out, but before outreach procedures were commenced) and the same four baseline measures. Where relationships of interest were found, multiple logistic regression was used to further analyse the relationships between attrition and the relevant baseline variables. All predictor variables were entered simultaneously.

Power analyses were conducted using the software package G*Power (version 3.1.9.2; Faul, Erdfelder, Lang, & Buchner, 2007). With power set at .80, and an alpha of .05, a sample size of 54 would be required to detect differences with a medium affect size (OR = 2.5); a sample of 28 would be required to detect differences with a large effect size (OR = 4.3). This study was therefore powered to detect differences of a medium-to-large effect size (allowing for expected attrition).

Adherence and outcome. Partial (Pearson) correlations were calculated separately for the relationships between the three measures of adherence (number of completed modules; number of modules started but not completed; and number of telephone sessions completed) and outcome on the EPDS, controlling for baseline depression. Separate calculations were made at all three time-points (17 weeks, 10 months, and 16 months post-randomisation). Where relationships of interest were found, further exploration was planned using multiple linear regression. With power set at .80 and an alpha of .05, a sample size of 25 would be required to detect differences with a large affect size. This study was therefore only powered to detect differences with a large

effect size.

Results

Feasibility of Long-Term Follow-Up

Prior to the commencement of outreach strategies to encourage outcome measure completion, 28% of the 83 randomised participants had completed an EPDS at 16 month follow-up (n = 23). When outreach strategies were utilised, this increased to 71% completion at 16 month follow-up (n = 59). Outreach completion rates at 16 months for the GAD-7, WSAS, and BADS were 63% (n = 52), and 60% (n = 50), and 59% (n = 49) respectively. The drop off in completion rates reflected the ordering of the questionnaires during data collection, with the EPDS in particular prioritized during outreach because it was the primary outcome measure. Non-outreach data were not available for the other time points as usage was not recorded until 16 month follow-up. Outreach completion rates at 10 months for the EPDS, GAD-7, WSAS, and BADS were 69% (n = 57), 39% (n = 32), 39% (n = 32), and 36% (n = 30), respectively. Outreach completion rates at 17 weeks for the EPDS, GAD-7, WSAS, and BADS were 86% (n = 71), 71% (n = 59), 71% (n = 59), and 71% (n = 59) respectively. (For baseline participant demographics see O'Mahen, Richards, et al., 2013).

Treatment Effect Size

Table 1 displays means and standard deviations for treatment and control groups. Small (non-significant) Cohen's *d* effect sizes favouring treatment were found for EPDS (-0.22, 95% CI [-0.72, 0.30]) and BADS (0.2, 95% CI [-0.37, 0.76]) scores. The effect sizes for GAD-7 (-0.06, 95% CI [-0.60, 0.48]) and WSAS (-0.08, 95% CI [-0.63, 0.48]) scores were minimal. Table 2 displays frequencies of participants with probable depression at each time-point,

alongside frequencies of participants who have relapsed at 10 and 16 months post-treatment, having been well at the previous time-point. There was a small (non-significant) effect of intervention on likelihood of probable depression, OR = 1.43, 95% CI [0.39, 5.27].

Table 1

Means and Standard Deviations for EPDS, BADS, GAD-7 and WSAS

		Assessment timing								
				17 weeks post-randomisation		10 months post-randomisation		16 months post-randomisation		
Measure	Condition	Baseline								
		Mean (*SD*)	*n*	Mean (*SD*)	*n*	Mean	(*SD*)	*n*	Mean (*SD*)	*n*
EPDS	INT	20.27 (3.26)	41	11.05 (4.71)	37	8.26	(5.5)	31	9.03 (4.22)	29
	TAU	21.07 (3.2)	42	14.26 (5.11)	34	11.35	(6.54)	26	10.17 (6.1)	30
BADS	INT	60.20 (20.1)	41	90.42 (22.4)	31	101.17	(32.03)	18	100.48 (24.77)	23
	TAU	58.62 (19.45)	42	76.64 (27.8)	28	98.00	(24.65)	12	94.96 (29.75)	26
GAD-7	INT	13.09 (3.82)	41	8.71 (4.61)	31	5.72	(4.76)	18	7.35 (5.48)	26
	TAU	14.12 (4.78)	42	11.29 (5.5)	28	8.57	(6.14)	14	7.69 (5.96)	26
WSAS	INT	4.72 (1.21)	41	3.19 (1.7)	31	2.44	(1.89)	18	2.54 (1.82)	24
	TAU	4.77 (1.54)	42	4.13 (1.76)	28	2.81	(1.84)	14	2.68 (1.93)	26

Note. EPDS, Edinburgh Postnatal Depression Scale; BADS, Behavioural Activation for Depression Scale; GAD-7, Generalized Anxiety Disorder Screener; WASAS, Work and Social Adjustment Scale; INT, NetmumHWD intervention; TAU, treatment as usual.

Adherence and Outcome

Table 3 displays the results of analyses to assess whether adherence to NetmumsHWD predicted outcome. None of the measures of adherence were significantly related to outcome on the EPDS. This was the case for all timings.

Table 2

Frequencies of Participants with Probable Depression, and Frequencies for Whom this Represents a Relapse Compared to the Previous Time-Point

	Assessment timing				
Condition	17 weeks post-randomisation	10 months post-randomisation		16 months post-randomisation	
	depressed (n)	depressed (n)	relapsed (n)	depressed (n)	relapsed (n)
INT	14 (37)	6 (31)	2 (31)	5 (29)	2 (29)
TAU	23 (34)	9 (26)	2 (25)	7 (30)	0 (28)

Note. INT, NetmumHWD intervention; TAU, treatment as usual.

Table 3

Partial Pearson Correlations for the Relationship Between Adherence and Outcome on the EPDS

	Assessment timing								
Adherence measure	17 weeks post-randomisation			10 months post-randomisation			16 months post-randomisation		
	r	*df*	*p*	*r*	*df*	*p*	*r*	*df*	*p*
Modules started (but not completed)	.139	32	.434	.002	26	.992	-.045	24	.826
Modules completed	-.053	32	.765	.041	26	.836	-.033	24	.872
Telephone sessions completed	.160	29	.389	-.046	24	.824	-.120	23	.511

Note. EPDS, Edinburgh Postnatal Depression Scale.

Predictors of Attrition

Tables 4 and 5 display the results from the analyses of baseline predictors of attrition. There were no significant differences between those that completed the EPDS at each time point and those that did not on any of the baseline socio-demographic or psychometric measures.

Further analyses were conducted to look for differences between participants that completed the 16 month EPDS independently (unaided participants), and those that did not complete independently, and thus required outreach (outreach participants; the latter includes those that did not complete

Table 4

One-Way ANOVA and Chi-Square Results for Relationship Between Baseline Factors and Attrition With and Without Outreach

	Total attrition									Unaided attrition		
	Assessment timing post-randomisation									Assessment timing post-randomisation		
	17 weeks			10 months			16 months			16 months		
Baseline measure	*F*	*df*	*p*	*F*	*df*	*p*	*F*	*df*	*p*	*F*	*df*	*p*
EPDS	0.37	1	.547	0.08	1	.775	0.00	1	.958	4.38	1	.040
BADS	0.66	1	.420	0.00	1	.987	0.35	1	.553	4.99	1	.028
SPS	0.00	1	.989	1.74	1	.191	0.25	1	.616	0.03	1	.867
Household income	1.17	1	.284	1.11	1	.295	2.30	1	.134	0.04	1	.846
	Fisher's Exact Test (one-sided)											
Relation-ship status			.266			.381			.103			.093

Note. EPDS, Edinburgh Postnatal Depression Scale; BADS, Behavioural Activation for Depression Scale; SPS, Social Provisions Scale.

Table 5

Multiple Logistic Regression Results for Relationship Between Baseline Factors and Attrition Prior to Outreach 16 Months Post-Randomisation

Baseline Factor	*B*	Wald χ^2	*p*	OR [95% CI]
EPDS	-0.11	1.61	.205	0.90 [0.75, 1.06]
BADS	0.02	0.02	.162	1.02 [0.99, 1.06]
SPS	-0.02	0.03	.344	0.98 [0.93, 1.03]
Household income	-0.02	0.10	.886	0.96 [0.80, 1.21]

Note. EPDS, Edinburgh Postnatal Depression Scale; BADS, Behavioural Activation for Depression Scale; SPS, Social Provisions Scale. OR, odds ratio; CI confidence interval.

at all but nonetheless received outreach). Outreach participants were significantly more likely to have a higher baseline EPDS (M = 21.18, SD = 3.75) score than unaided participants (M = 19.35, SD = 3.07), $F(1,81) = 4.38$, p = .040. They were also significantly more likely to have lower baseline levels of behavioural activation (M = 56.48, SD = 19.42) than those who completed unaided (M = 67.00, SD = 18.63), $F(1,81) = 4.99$, p = .028. However, when

considered together in regression analyses, there was no significant independent prediction by baseline variables. Furthermore, there were no significant differences between unaided participants and outreach participants on the psychometric measures of perceived social support or functional impairment, or in relation to household income. However, there was a marginally significant difference between single participants and those in a relationship: unaided participants were slightly more likely to be in a relationship than those that required outreach, $p = .093$ (one-sided Fisher's Exact Test); none of the unaided participants were single (see Table 6).

Table 6

Frequencies of Participants who had Disengaged Prior to Outreach Provision by Relationship Status 16 Months Post-Randomisation

	Relationship status	
EPDS completion category	Single	In a relationship
Unaided	0	23
Required outreach	7	53

Note. EPDS, Edinburgh Postnatal Depression Scale.

Discussion

Importantly, results showed that long-term follow-up of depressed postnatal mothers in a trial of supported online behavioural activation for depression was feasible. Although attrition was towards the high end in terms of previous internet-based follow-up research (see, e.g., Mackinnon et al., 2008), it was in line with research on postnatal populations (see Sockol et al., 2011). This is encouraging given the dearth of research into long-term follow-up in women with postnatal depression (Dennis & Hodnett, 2007; Sockol et al., 2011). In order to achieve this level of trial retention, considerable outreach was required at 16 month follow-up. This included email, text and telephone contact

with participants, with high levels of flexibility in the timing of contacts, including the provision of contact during evenings and at weekends. Nonetheless, the provision of outreach approximately doubled EPDS completion rates at 16 months suggesting outreach is an effective means of decreasing trial attrition, including the systematic attrition of individuals with more severe depressive symptomology and lower levels of behavioural activation. The current data provides useful information for a Phase III trial, as it suggests that use of outreach strategies for data collection might ensure that results are representative of the population. Thus any roll out of treatment programmes based on such research may be applicable to the widest possible proportion of society. Thus the need for additional, outreach research work, possibly outside of normal office hours, may need to be factored into future research proposals and grant applications.

The differential effects of outreach were of theoretical interest. It may be that study participation was not (perceived as) a source of positive reinforcement for the more severely-depressed mothers, nor for those with the lowest levels of behavioural activation, and thus they initially withdrew from participation-based activity in order to better cope. This possibility is in line with my predictions. However, the provision of outreach appears to have been enough to counter the initial reduction in activity and thus produce more equal participation in these groups. A similar trend was found for relationship status: participants who were in a relationship were slightly more likely to complete the 16 month follow-up EPDS unaided, although this finding only approached significance. It was possible that the lack of social resources that came from being single meant single mothers were simply too busy and/or exhausted to (remember to) take part without additional (social) encouragement. It is

interesting to note that a similar trend was not found for perceived social support, so perhaps the actual presence of support is more important than the perceived presence; for instance, in order to have sufficient free time and/or energy to participate in research, actual sharing of household tasks, etc., becomes important, and this may be more likely when in a relationship than with plentiful perceived support. However, this result should be treated with caution as only seven participants were single in total, thus variability was low. There was no significant independent prediction of attrition in the regression equation. This may, in part, be due to shared variance between the variables, particularly between EPDS and BADS scores. However, the study was also insufficiently powered to detect either smaller or medium-sized effects.

It was highly encouraging to find that postnatal women remained in the NetmumsHWD study regardless of baseline depression, behavioural activation, household income, relationship status, and perceived social support, at all time-points. This suggests that participants did not differentially drop out of the trial, and that perhaps the protocol was found to be sufficiently amenable to all groups. This is particularly encouraging in terms of the potential generalizability of Phase III results if a similar methodology is utilised. However, these findings should be taken with caution as the study was only powered to detect large effects, and thus small to moderate effects of baseline factors on attrition may have been missed.

Although the effect size for depressive symptoms at follow-up was low, this finding is in line with the findings of a recent meta-analysis on eCBT for depression more broadly (So et al., 2013; although this study has been criticised for basing follow-up conclusions on a small overall sample; Christensen & Mackinnon, 2013). Furthermore, the low effect size is perhaps

unsurprising given the low mean 16 month EPDS scores for both control and intervention groups, demonstrating that many of the mothers in the control group, while untreated, had nonetheless recovered. Indeed, this is in keeping with research suggesting that for many women depressive symptoms remit naturally over the course of the postnatal period (Heron, O'Connor, Evans, Golding, & Glover, 2004). However, it is important to note that the effect size differences in women's depression scores was large at both 17 weeks and 10 months (O'Mahen, Richards, et al., 2013), demonstrating that the NetmumsHWD reduced women's depression scores more quickly than women in TAU. Further, women's depression scores in the NetmumsHWD condition did not worsen over time. This is significant, given that chronicity is symptoms is a predictor of future relapse, and given the negative affect of PND on the development of the mother-infant relationship and subsequent child outcomes. If confirmed in a larger RCT, future research should also investigate the relationship between speed of improvement and its impact on the wellbeing of the infant and family, as well as the cost-effectiveness implications of a speedier recovery.

There was no evidence that any of the three measures of adherence predicted depression outcome at any of the three measurement time points. Although this is in contradiction to some internet-based studies, which have found a relationship between number of modules completed and treatment outcome (n = 5), the finding that number of telephone sessions does not predict outcome is in line with findings from face-to-face studies of depression that number of sessions does not predict outcome (Cuijpers, Huibers, Ebert, Koole, & Andersson, 2013; Donkin et al., 2011). However, there are some inconsistencies within the literature; in a more recent RCT of an internet-based

treatment for depression, number of modules completed was not independently associated with outcome, while a new measure of number of activities completed per log-in was (Donkin et al., 2013).

These findings suggest a more complicated relationship between adherence and outcome than has been understood to date. Further, it gives support to the emerging idea that it is the level of engagement in a treatment (defined as “behavioural participation”), rather than simply adherence per se, that is of particular importance in terms of outcome (Tetley, Jinks, Huband, & Howells, 2011). For instance, preliminary research suggests that between-session CBT skill usage, a key component of engagement, might be an important mediating factor on outcome (Hundt, Mignogna, Underhill, & Cully, 2013). Key factors of engagement proposed to date relate to attendance at requisite sessions, completion of treatment within the expected timeframe, completion of homework tasks, contribution to therapy sessions (such as completion of tasks), an appropriate working alliance with the therapist(s), and, for groups, a working alliance with other members (Tetley et al., 2011). Thus Phase III researchers might choose to adapt a measure of engagement for use in online research. However, there is little consensus as to which measure is most appropriate, and many engagement measures only assess single components of engagement (if any), or are not accompanied by assessments of reliability or validity (Tetley et al., 2011). Thus the selection or development of an appropriate engagement measure for Phase III research is likely to prove a challenge to researchers.

Limitations

This study was designed to assess the feasibility of long-term follow-up, and thus does not provide definitive outcomes on the effectiveness of the

NetmumsHWD intervention; a Phase III trial is required before firm conclusions can be drawn. Further, due to its small sample size, this study was only powered to detect large effects in terms of adherence and predictors of attrition, and thus smaller effects may have been missed. Results should therefore be taken as preliminary and should provide a starting point for more detailed research with larger samples.

This study did not assess whether improvements in behavioural activation and/or depressive symptomology post-treatment affected the likelihood of attrition at follow-up. The current study would have been underpowered to do this, but it would be appropriate for a Phase III trial. This line of research would help to further the theoretical underpinnings of attrition research so that, in turn, better interventions could be designed in order to minimise attrition.

Furthermore, this study did not assess the feasibility of investigating relapse rate via diagnostic interview, which is an important outcome in depression research. Future research should therefore expand upon the outcomes addressed in the current study to include a diagnostic measure of relapse at follow-up. This may require a longer period of follow-up.

It should be noted that the use of pilot study effect sizes in Phase III sample size estimation, although common practice, has been criticised by some as an unreliable methodology (Leon, Davis, & Kraemer, 2011). Specifically, the small sample sizes usually found in pilot studies may produce biased effect size estimates, and should thus only be used as one small part of future sample size calculations. Thus, rather than relying on precise figures, researchers should merely be guided by the estimations; for instance, the estimated presence in the current study of small effect sizes with wide confidence intervals at 16 month follow-up might guide Phase III researchers to inflate sample size estimations

produced by standard power calculations, if planning to conduct longer-term follow-up.

Finally, recruited mothers were existing users of the Netmums website, so NetmumsHWD may not generalise to mothers who do not so readily seek support and information from an online platform. It therefore remains to be seen whether NetmumsHWD might prove a feasible intervention for postnatal mothers across the board.

Conclusions

In conclusion, this study has found that long-term follow-up of mothers with postnatal depression is feasible. This study has therefore provided useful information for the planning of a Phase III trial of NetmumsHWD, particularly in terms of the importance of outreach. In particular, outreach strategies may be sufficient to prevent the differential attrition of mothers with high depressive symptomology and low levels of behavioural activation. In summary, online behavioural activation appears to be suitable for a broad spectrum of women, and it may speed up recovery from postnatal depression.

Ethical Approval and Considerations

Ethical approval for this research was obtained from the University of Exeter Psychology Research Ethics Committee (reference number 2010/269). Participants were provided with written participant information at the start of the study. This outlined possible risks, such as the time-consuming nature of an online intervention, and the possibility of emotional distress when thinking about or discussing personal issues. Participants were made aware that the telephone support workers and researchers were fully trained to discuss sensitive issues to minimise any distress, and that answering questions that caused distress was not compulsory (although they were informed that the latter would have

meant difficulties with continuing with the trial). They were made aware that they could withdraw themselves from the study at any time by contacting the team or by filling out the relevant form on the online system. All participants gave their full informed consent for participation by signing the online consent form.

Acknowledgements

This trial was conducted with funding from the National Institute for Health Research (NIHR) Collaboration for Leadership in Applied Health Research and Care (CLAHRC) for the South West Peninsula. The views expressed in this publication are those of the author and not necessarily those of the National Health Service (NHS), the NIHR or the Department of Health in England.

Conflict of Interest

The author has no conflict of interest to declare.

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Appendix A

Copy of the Ethical Approval Documentation

Psychology Research Ethics Committee

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To: **Heather O'Mahen**
From: **Cris Burgess**
CC: **David Richards**
Re: **Application 2010/269 Ethics Committee**
Date: **July 29, 2014**

The School of Psychology Ethics Committee has now discussed your application, ***2010/269 – Netmums: A pilot randomised controlled trial (RCT) to investigate the feasibility and effectiveness of an online Behavioural Activation (iBA) intervention, supported over the telephone, in comparison to treatment-as-usual (TAU).*** The project has been approved in principle for the duration of your study. Although not a condition of approval, we feel that the time required to complete the interviews and questionnaires wasn't clear in the Information Sheet. We feel this should be specified, given there are quite a few questionnaires and the interview is fairly lengthy.

The agreement of the Committee is subject to your compliance with the British Psychological Society Code of Conduct and the University of Exeter procedures for data protection (http://www.ex.ac.uk/admin/academic/datapro/). In any correspondence with the Ethics Committee about this application, please quote the reference number above.

I wish you every success with your research.

Cris Burgess
Chair of Psychology Research Ethics Committee

Appendix B

Copy of the Online Participant Information Sheet

Netmums Helping with Depression Study

Thank-you for your interest in taking part in the Netmums Helping with Depression Research Study. Before you agree to take part in this study it is really important for you to understand more about the study and what being involved will mean. Please read this information sheet carefully before you decide whether or not to take part. In order to read each section, select a question from the left and the information will pop up.

You may also like to discuss taking part in this research with your family, friends, GP or Health Visitor. If you have any questions at all after reading this please feel free to contact the research team directly (contact details are at the bottom of this page).

What is the purpose of the study?

What are the treatments being studied?

Do I have to take part?

What will happen if I take part? What will I have to do?

What information do you want to know about me?

Will I be in the online CBT programme group or the group continuing to receive usual care? How is this decided?

What does taking part in the online CBT programme group on the group continuing to receive usual care involve?

How will you check to see how I am getting on?

What are the possible disadvantages and risks of taking part?

What are the possible benefits of taking part?

What happens when the research study stops?

What if new information becomes available?

What if something goes wrong?

Will my taking part in this study be kept confidential?

What will happen to the results of the research study?

Who is organising and funding the research? Who has reviewed the study?

What happens next?

What if I have any questions or concerns either now or in the future?

What is the purpose of the study?

Postnatal depression is very common. There are many changes that happen when you have a baby. Your lifestyle, your role in life, the type and hours of work you do, your relationships, sleep patterns, and hormone levels all change. Although motherhood may bring much happiness, it is understandable that, faced with all these changes, many women find that they struggle with depression as well as irritable, anxious and sad moods. If you are one of those women it is absolutely not your fault.

Also, many women with low mood experience difficulty accessing appropriate psychological treatment. When we are a busy mum it can be really hard to find time to see a therapist of a counsellor – or find someone to care for our baby when we do. Also there are sometimes very long waiting lists to see someone. Some mums also find it difficult to speak to people about feeling low or depressed and don't feel comfortable taking to health professionals.

An online cognitive behavioural therapy (CBT) programme for postnatal depression, supported over the telephone, may help with some of these difficulties. There is evidence to suggest that supported online programmes can help improve how people feel but this has not yet been studied in women experiencing postnatal depression.

We are interested in comparing the online programme, supported over the telephone for 12 weeks, with the usual care women with postnatal depression receive.

This study is an extension to some studies we ran between 2009 and 2011. During these studies we compared an older version of the current online programme with usual care currently received by women with postnatal depression. 384 women completed the study with 66% of women receiving the online intervention for 12 weeks no longer experienced postnatal depression at the end of receiving treatment, compared with 46% of women who received usual care.

Although these studies suggest that the online intervention is more effective than usual care for women with postnatal depression we know from other research studies that online interventions can be even more effective when support is received from a mental health care professional. This new study will see whether providing telephone support increases the effectiveness of the programme. We will also look to see if the effects last for longer than 12 weeks and therefore the study will last for 12 months.

What are the treatments being studied?

We are comparing an online cognitive behavioural therapy (CBT) programme, which is based on a specific type of CBT – behavioural activation (BA)- supported over the telephone with the usual care received for postnatal depression. Earlier studies have found that BA is effective in helping people suffering from low mood feel better.

The Online CBT Programme

Online treatments based on CBT are currently recommended by NICE for the treatment of depression however currently no programmes exist for women who are experiencing postnatal depression.

The online CBT programme lasts for 12 weeks and support is provided over the telephone by a mental health professional, specially trained in providing support to this type of programme. There will be one telephone support session a week for the 12 weeks of the programme which will last for approximately 30 minutes. The telephone calls can be held at any time that is convenient, including during the evening or at the weekend. The support sessions mainly consist of helping mums work through the material and answering any questions that mums might have.

The online CBT programme is based on Behavioural Activation which is a Cognitive Behavioural Approach. It is focused on helping people improve how things are for them right now. There are two ways the approach can do this:

1 By helping you recognise how your mood is closely linked to the things with do – the programme is based on evidence which shows that if we change the way behave or mood can be lifted.

2 By helping you become more effectively involved in areas of your life that are important to you (e.g., improving your communication skills and getting support from those around you, in turn reducing isolation, and improving your relationship with your infant)

The online programme has a number of modules. The first module, which lasts over about 5 sessions, is based on helping you understand and work with the Behavioural Activation approach. You can then choose two additional modules to complete over the next 6 weeks which cover: anxiety; improving communication and support, changes in roles and relationships, problems with sleep, problems with negative thinking or worry which often occur when we are feeling low and parenting. In the final week you will complete a module on preventing depression in the future. At the end of the 12 weeks you can work through other modules but the telephone support sessions will only last for 12 weeks.

Continuing to Receive Usual Care

Usual care for postnatal depression could include a variety of things. You may receive care from your GP or your Health Visitor for example. Your GP may prescribe you with antidepressant medication or refer you to a mental health professional. Your Health Visitor may provide support during visits or encourage you to speak to your GP about other forms of treatment.

Do I have to take part?

No, it is up to you to decide whether or not to take part in the study. If you do decide to take part in this study we will take you through an online consent process. The consent process will confirm that you have agreed to enter the study and understand what taking part in the study involves.

If you decide to take part you are free to withdraw at any time and without giving a reason. The study clinician may also withdraw you from the study if they feel it would be in your best interests. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

What will happen if I take part? What will I have to do?

Taking part in this study involves a number of stages over the next 12 months:

1 Getting to know more about you

2 Receiving the online CBT programme with telephone support or continuing to receive usual care

3 The research team seeing how you are doing over the next 12 months

4 Some mums who receive the online CBT programme will be invited to take part in an interview to understand their experiences of using the online programme

Everyone who takes part in this research will be asked to complete some questionnaires online at the beginning of the study, at 5 weeks into the study and 3, 6 and 12 months later. You will also be asked to speak to a researcher over the telephone at the beginning of the study, and 3, 6 and 12 months later to understand more about you and how you are getting on. These telephone calls are all extra from what you would normally have for the management of your depression.

Those mums allocated to receive the online programme will receive 12 telephone support sessions lasting 30 minutes each during each week of the 12 week programme.

Some mums who receive the online programme will be invited to participate in a telephone interview after they have finished the 12 weeks of treatment. This will be with a researcher and will consist of questions about your experience of using the programme and the telephone support sessions.

What information do you want to know about me?

The first thing we will want to do is to find out a bit more about you.

First we need to check that you are suitable for this study. We will firstly ask you to complete some questions online about your current and past mental health, current symptoms, current relationships, support you receive and some questions around you and your baby. We will also ask you to give us some information about your age, occupation, marital status, home background, education and treatments you may have already received for your depression. If you would rather speak to a researcher over the telephone, some of these questions can be filled out over the telephone instead. These questionnaires will take around 30 minutes to 1 hour to complete. These questions are important

so we can understand how you are doing currently. They will also help us to see if the programme helps you or not.

We will then need to speak you over the telephone to ask you some more questions about your current and past mental health, what experiences you have had of depression and how this affects you. We expect these questions to take between 1 and 2 hours. We understand that finding 1 -2 hours when you are a busy mum can be really tough so we can call you at a time convenient to you – which includes evenings or weekends. We can also hold the interview over a couple of telephone calls if this helps.

If you are suitable and would like to take part in the trial you will need to log onto the study website and complete a final consent form.

With your permission, we would like to audiotape the telephone call to make sure that the researchers are doing a good job. These audiotapes will be stored securely in a locked cabinet in the Mood Disorders Centre and will be accessible only to members of the research team. You can however opt out of having the telephone calls taped if you wish to.

Will I be in the online CBT programme group or the group continuing to receive usual care? How is this decided?

After you have completed all of the questionnaires and the questions of the telephone with a researcher you will need to log back onto the website and complete a final consent form. The website will tell you whether you have been allocated to receive the online programme with telephone support, or to continue receiving usual care.

Because we don't know whether the online CBT programme with telephone support is better than the usual care provided for postnatal depression we need to make comparisons. This is why some mums will receive the online programme with telephone support and why other mums will continue to receive usual care – then we can compare the two groups to see which one is better.

The groups are selected randomly – by chance. You have a 50% change of being allocated to the online programme with telephone support and a 50% change of being allocated to continue to receive usual care.

What does taking part in the online CBT programme group on the group continuing to receive usual care involve?

Online CBT Programme: If you are in this group you will be provided with a web link to the online programme, which is only available to mums in this study who are randomly allocated to this group. You will need to register for the online programme and can then start working though the modules over the 12 weeks of the course.

When allocated to receive the online CBT programme you will be asked to provide some days and times that would be suitable to be contacted by the person providing the telephone support so that you can organise your first telephone support session. With your permission, each telephone support

session will be recorded so we can make sure that the telephone supporters are doing a good job. If you don't want the telephone support sessions to be recorded this is fine too. As with all out tapes, these will be stored in a locked cabinet in the Mood Disorders Centre.

Continuing Usual Care: if you are in this group you will continue to receive the standard care you are currently receiving for your postnatal depression. This may include care through your GP or Health Visitor. The usual care you receive may change during the course of the study so we will ask some questions around this when we contact you during the 12 months to find out how you are getting on.

You will also gain access to the Netmums Coping with Depression open forum.

How will you check to see how I am getting on?

You will be given a set of questionnaires online and asked some questions over the telephone about how you are doing over the next 12 months. We will normally do this after 5 weeks, and after 3, 6 and 12 months.

We would also like to ask some mums who receive the online CBT programme with telephone support about their experiences of using the programme. If you are one of the mums chosen to do this, we will invite you to have a chat over the telephone with one of our researchers about your experiences. We would want to find out about what you thought about the online CBT programme and telephone support – what was useful and also what was not useful. We would like to audiotape these with your permission. These tapes will be stored in a locked cabinet in the Mood Disorders Centre and will be accessible only to members of the research team.

What are the possible disadvantages and risks of taking part?

Taking part in this study will involve you taking some time to complete the questionnaires and talk to the researchers over the telephone about how you are getting on. As these questions are about you some of the questions are personal and it can be upsetting to discuss these issues. You don't have to discuss anything you don't want to and the researchers are trained to make sure that they are sensitive to your feelings and concerns.

If you are in the online CBT programme and telephone support group you will have to agree to work through the programme and attend the telephone support sessions. You will also need to complete exercises and practice the new skills and techniques you learn during the programme. Taking part in the online programme does involve time, effort and commitment, however many people who have used the programme have found it worthwhile, and it has helped them with their low mood. We have designed the course with other mothers who have taken the course in the past to make sure that the materials and work are not too burdensome.

What are the possible benefits of taking part?

We hope that either continuing normal care or the online CBT programme with telephone support will help you with your postnatal depression. Online CBT is recommended for depression by NICE (The National Institute for Clinical Excellence) and the continued usual care received may include other treatments recommended by NICE. However, we cannot guarantee that these treatments will help you.

The information we get from this study will help us to treat future mums experiencing postnatal depression better. We will keep an eye on everyone in the study to see how they are doing and if they show signs of severe deterioration we will help ensure they have access to appropriate help.

What happens when the research study stops?

At the end of the study you should discuss with your GP or health visitor how to continue your treatment plan.

Those allocated to the online CBT programme can continue to use the programme whenever they wish.

At the end of the 12 months, those mums allocated to the usual care group will also be able to access the online CBT programme – but this will not be part of this research study.

What if new information becomes available?

Sometimes during the course of a research study new information becomes available about the treatment which is being studied. If this does happen, we will tell you about it and discuss with you whether you would like to continue in the study. If you decide to continue in the study you would need to sign a new consent form. Sometimes when we receive new information we may consider it to be suitable to withdraw you from the study. If this happens we will explain the reasons and provide you with alternative sources to gain support from.

What if something goes wrong?

If you are experiencing problems or you feel that something is going wrong then please let us know immediately and we will do our very best to deal with the issue properly.

You can talk to your telephone supporter if you are in the online CBT programme and whichever group you are in your can contact the research team. You can also contact the Principal Investigator, Dr Heather O'Mahen, on h.o'mahen@exeter.ac.uk or 01392 724651. If you wish to complain about any aspect of the research team's work you can also raise this with Dr Heather O'Mahen or with Netmums.

Will my taking part in this study be kept confidential?

All information collected about you during the course of the research will be kept strictly confidential. Information about you will have your name / email removed so that you cannot be recognised from it. Any personal details will be

stored in a separate locked cabinet from all the information we collect and we never put your name on any of the questionnaires we ask you to fill out. The only exception would be if the questionnaires, interview or support sessions (if allocated to the online CBT programme) revealed a significant risk of harm to yourself or others, in which can information may be fed back to your doctor but normally only after discussion with you.

What will happen to the results of the research study?

The researchers will aim to present this work at conferences and to publish it in an academic journal. We will also provide all those who take part with regular newsletters during the 12 months of the trial with updates. At the end of the study you will also be sent an information sheet detailing the results we have found. Your identity will never be revealed in any report of publication.

Who is organising and funding the research? Who has reviewed the study?

The research is jointly funded by PenCLAHRC – the Peninsula Collaboration for Leadership in Applied Health Research and Care and the University of Exeter. The research has been approved by the University of Exeter, School of Psychology Ethics Committee.

What happens next?

You will need to click on the link at the bottom of the webpage to take you through to the online consent process and the online questionnaires. If you are still happy and suitable to take part you will then have a telephone meeting with one of the researchers to complete the process of getting to know you a little better.

What if I have any questions or concerns either now or in the future?

If you have any questions or concerns please feel free to talk to the Netmums Study research team:

The NETMUMS Trial

Mood Disorders Centre

College of Life and Environmental Sciences

Washington Singer Laboratories

University of Exeter

EX4 4QG

Telephone: 01392 XXX XXX

Email: Netmums.HelpingStudy@exeter.ac.uk

Any questions, concerns or complaints can also be addressed to Dr Heather O'Mahen, the Principal Investigator for the study:

Dr Heather O'Mahen

Mood Disorders Centre

College of Life and Environmental Sciences

Washington Singer Laboratories

University of Exeter

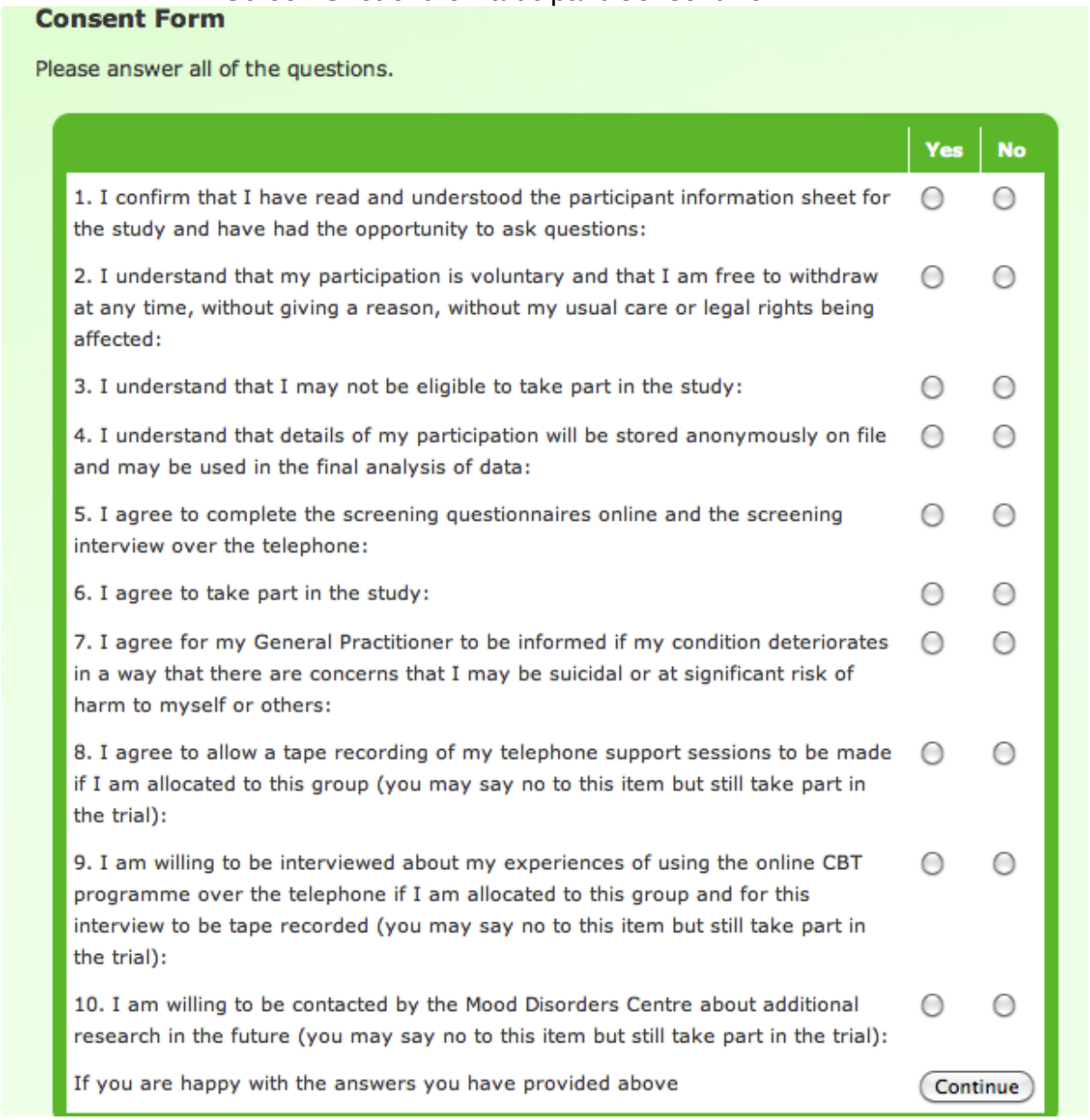
EX4 4QG

Telephone: 01392 724651

Email: h.o'mahen@exeter.ac.uk

Appendix C

Screen Shot of the Participant Consent Form



Consent Form

Please answer all of the questions.

	Yes	No
1. I confirm that I have read and understood the participant information sheet for the study and have had the opportunity to ask questions:	○	○
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason, without my usual care or legal rights being affected:	○	○
3. I understand that I may not be eligible to take part in the study:	○	○
4. I understand that details of my participation will be stored anonymously on file and may be used in the final analysis of data:	○	○
5. I agree to complete the screening questionnaires online and the screening interview over the telephone:	○	○
6. I agree to take part in the study:	○	○
7. I agree for my General Practitioner to be informed if my condition deteriorates in a way that there are concerns that I may be suicidal or at significant risk of harm to myself or others:	○	○
8. I agree to allow a tape recording of my telephone support sessions to be made if I am allocated to this group (you may say no to this item but still take part in the trial):	○	○
9. I am willing to be interviewed about my experiences of using the online CBT programme over the telephone if I am allocated to this group and for this interview to be tape recorded (you may say no to this item but still take part in the trial):	○	○
10. I am willing to be contacted by the Mood Disorders Centre about additional research in the future (you may say no to this item but still take part in the trial):	○	○
If you are happy with the answers you have provided above	Continue	

Appendix D

Study Measure: Edinburgh Postnatal Depression Scale

Please select the answer which comes closest to how you have felt **in the past 7 days**, not just how you feel today.

1. I have been able to laugh and see the funny side of things.

   ___ As much as I always could
   ___ Not quite so much now
   ___ Definitely not so much now
   ___ Not at all

2. I have looked forward with enjoyment to things.

   ___ As much as I ever did
   ___ Rather less than I used to
   ___ Definitely less than I used to
   ___ Hardly at all

3. I have blamed myself unnecessarily when things went wrong.

   ___ Yes, most of the time
   ___ Yes, some of the time
   ___ Not very often
   ___ No, never

4. I have been anxious or worried for no good reason.

   ___ No, not at all
   ___ Hardly ever
   ___ Yes, sometimes
   ___ Yes, very often

5. I have felt scared or panicky for not very good reason.

   ___ Yes, quite a lot
   ___ Yes, sometimes
   ___ No, not much
   ___ No, not at all

6. Things have been getting on top of me.

   ___ Yes, most of the time I haven't been able to cope at all
   ___ Yes, sometimes I haven't been coping as well as usual
   ___ No, most of the time I have coped quite well
   ___ No, I have been coping as well as ever

7. I have been so unhappy that I have had difficulty sleeping.

___ Yes, most of the time
___ Yes, sometimes
___ Not very often
___ No, not at all

8. I have felt sad or miserable.

___ Yes, most of the time
___ Yes, quite often
___ Not very often
___ No, not at all

9. I have been so unhappy that I have been crying.

___ Yes, most of the time
___ Yes, quite often
___ Only occasionally
___ No, never

10. The thought of harming myself has occurred to me.

___ Yes, quite often
___ Sometimes
___ Hardly ever
___ Never

Appendix E

Study Measure: Behavioural Activation for Depression Scale

Please read each statement carefully and then circle the number which best describes how much the statement was true for you DURING THE PAST WEEK, INCLUDING TODAY.

	Not at all		A little		A lot		Completely
1. I stayed in bed for too long even though I had things to do	○	○	○	○	○	○	○
2. There were certain things I needed to do that I didn't do	○	○	○	○	○	○	○
3. I am content with the amount and type of things I did	○	○	○	○	○	○	○
4. I engaged in a wide and diverse array of activities.	○	○	○	○	○	○	○
5. I made good decisions about what type of activities and/or situations I put myself in.	○	○	○	○	○	○	○
6. I was active, but did not accomplish any of my goals for the day.	○	○	○	○	○	○	○
7. I was an active person and accomplished the goals I set out to do.	○	○	○	○	○	○	○
8. Most of what I did was to escape from or avoid something unpleasant.	○	○	○	○	○	○	○
9. I did things to avoid feeling sadness or other painful emotions.	○	○	○	○	○	○	○
10. I tried not to think about certain things.	○	○	○	○	○	○	○
11. I did things even though they were hard because they fit in with my long-term goals for myself.	○	○	○	○	○	○	○
12. I did something that was hard to do but it was worth it.	○	○	○	○	○	○	○
13. I spent a long time thinking over and over about my problems.	○	○	○	○	○	○	○
14. I kept trying to think of ways to solve a problem but never tried any of the solutions.	○	○	○	○	○	○	○
15. I frequently spent time thinking about my past, people who have hurt me, mistakes I've made, and other bad things in my history.	○	○	○	○	○	○	○
16. I did not see any of my friends.	○	○	○	○	○	○	○
17. I was withdrawn and quiet, even around people I know well.	○	○	○	○	○	○	○
18. I was not social, even though I had opportunities to be.	○	○	○	○	○	○	○
19. I pushed people away with my negativity.	○	○	○	○	○	○	○
20. I did things to cut myself off from other people.	○	○	○	○	○	○	○
21. I took time off of work/school/chores/responsibilities simply because I was too tired or didn't feel like going in.	○	○	○	○	○	○	○
22. My work/schoolwork/chores/responsibilities suffered because I was not as active as I needed to be.	○	○	○	○	○	○	○
23. I structured my day's activities.	○	○	○	○	○	○	○
24. I only engaged in activities that would distract me from feeling bad.	○	○	○	○	○	○	○
25. I began to feel badly when others around me expressed negative feelings or experiences.	○	○	○	○	○	○	○

Appendix F

Study Measure: Generalised Anxiety Disorder Scale

Over the last 2 weeks, how often have you been bothered by the following problems?	Not at all	Several days	More than half the days	Nearly every day
1. Feeling nervous, anxious or on edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Worrying too much about different things	0	1	2	3
4. Trouble relaxing	0	1	2	3
5. Being so restless that it is hard to sit still	0	1	2	3
6. Becoming easily annoyed or irritable	0	1	2	3
7. Feeling afraid as if something awful might happen	0	1	2	3

Appendix G

Study Measure: Work and Social Adjustment Scale

People's problems sometimes affect their ability to do certain day-to-day tasks in their lives. To rate your problems look at each section and determine on the scale provided how much your problem impairs your ability to carry out the activity.

1. **WORK** - if you are retired or choose not to have a job for reasons unrelated to your problem, please choose N/A (not applicable)

0	1	2	3	4	5	6	7	8	N/A
Not at all		Slightly		Definitely		Markedly	Very severely, I cannot work		

2. **HOME MANAGEMENT** – Cleaning, tidying, shopping, cooking, looking after home/children, paying bills etc

0	1	2	3	4	5	6	7	8
Not at all		Slightly		Definitely		Markedly	Very severely	

3. **SOCIAL LEISURE ACTIVITIES -** With other people, e.g. parties, pubs, outings, entertaining etc.

0	1	2	3	4	5	6	7	8
Not at all		Slightly		Definitely		Markedly	Very severely	

4. **PRIVATE LEISURE ACTIVITIES –** Done alone, e.g. reading, gardening, sewing, hobbies, walking etc.

0	1	2	3	4	5	6	7	8
Not at all		Slightly		Definitely		Markedly	Very severely	

5. **FAMILY AND RELATIONSHIPS –** Form and maintain close relationships with others including the people that I live with

0	1	2	3	4	5	6	7	8
Not at all		Slightly		Definitely		Markedly	Very severely	

Appendix H

Study Measure: Social Provisions Scale

1. There are people I can depend on to help me if I really need it.	○	○	○	○
2. I feel that I do not have close personal relationships with other people.	○	○	○	○
3. There is no one I can turn to for guidance in times of stress.	○	○	○	○
4. There are people who depend on me for help.	○	○	○	○
5. There are people who enjoy the same social activities I do.	○	○	○	○
6. Other people do not view me as competent.	○	○	○	○
7. I feel personally responsible for the well-being of another person.	○	○	○	○
8. I feel part of a group of people who share my attitudes and beliefs.	○	○	○	○
9. I do not think other people respect my skills and abilities.	○	○	○	○
10. If something went wrong, no one would come to my assistance.	○	○	○	○
11. I have close relationships that provide me with a sense of emotional security and well-being.	○	○	○	○
12. There is someone I could talk to about important decisions in my life.	○	○	○	○
13. I have relationships where my competence and skills are recognized.	○	○	○	○
14. There is no one who shares my interests and concerns.	○	○	○	○
	Strongly disagree	**Disagree**	**Agree**	**Strongly Agree**
15. There is no one who really relies on me for their well-being.	○	○	○	○
16. There is a trustworthy person I could turn to for advice if I were having problems.	○	○	○	○
17. I feel a strong emotional bond with at least one other person.	○	○	○	○
18. There is no one I can depend on for aid if I really need it.	○	○	○	○
19. There is no one I feel comfortable talking about problems with.	○	○	○	○
20. There are people who admire my talents and abilities.	○	○	○	○
21. I lack a feeling of intimacy with another person.	○	○	○	○
22. There is no one who likes to do the things I do.	○	○	○	○
23. There are people I can count on in an emergency.	○	○	○	○
24. No one needs me to care for them.	○	○	○	○

Appendix I

Dissemination Statement

This thesis will be adapted in line with journal requirements and submitted for publication to the Archives of Women's Mental Health. This journal has an international scope covering psychological, social, and biological aspects of all psychiatric and psychosomatic disorders that occur in women. In 2012 it had an impact factor of 2.009. It is therefore a highly appropriate journal in terms of maximizing the likelihood that this work will have an important impact. The findings will be presented to interested parties within the University of Exeter. They will also be published on the Netmums Facebook page, and in the participants' regular termly newsletter. Upon publication, Netmums will advertise the results on their webpage.

Appendix J

Note: Copy of Instructions to Authors from Archives of Women's Mental Health

A copy of the instructions to authors from the Archives of Women's Mental Health can be found in the appendix of the literature review.