A randomized controlled trial of smoking cessation for pregnant women to test the effect of a transtheoretical model-based intervention on movement in stage and interaction with baseline stage

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Objectives. To examine whether, as predicted by the transtheoretical model (TTM), stage-matched interventions will be more effective than stage-mismatched interventions.

Design. Randomized controlled trial of smoking cessation advice to pregnant smokers.

Methods. Pregnant women currently smoking at 12 weeks gestation were enrolled in a pragmatic three-arm trial of TTM-based interventions to help them stop smoking. One arm constituted standard midwifery advice and a self-help leaflet on stopping smoking, which is generally appropriate for women in preparation. Two arms were TTM-based. Differences in positive movement in stage towards quitting from enrolment to 30 weeks gestation and 10 days post-partum were calculated for each arm of the trial. We then examined whether, as predicted from the TTM, the relative benefit of the TTM-based intervention was greater for women in precontemplation and contemplation, for whom the control intervention was stage-mismatched, than for women in preparation, for whom the control intervention was stage-matched.

Results. Women in the TTM-based arms were statistically significantly more likely to move forward in stage than were women in the control arm. Contrary to the TTM-derived hypothesis, the greater relative benefit of the TTM-based intervention was seen for women in preparation stage at baseline, rather than women in precontemplation and contemplation.

Conclusions. The TTM-based intervention was more effective in stage movement, but this could be due to its greater intensity. The failure to confirm that stage-matching was important casts doubt on the validity of the TTM in explaining smoking cessation behaviour in pregnancy.

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Prochaska and Diclemente (1983) proposed the transtheoretical model (TTM) of behaviour change, suggesting that individuals who are changing their behaviour move through a series of stages. These are qualitatively distinct psychological states that manifest by intention and action in behaviour. Precontemplation is the stage in which individuals have no intention of changing their behaviour in the foreseeable future. In contemplation, individuals are considering it but are not committed to it, and in preparation, individuals are committing to and planning for imminent change. Action is the stage in which behaviour has changed, and maintenance is the stage in which the new behaviour is more entrenched (Prochaska & Velicer, 1997; Fig. 1). Furthermore, the TTM proposes that the psychological processes that are used to move from, say, precontemplation to contemplation, are different from those that move individuals from preparation to action (Prochaska & Velicer, 1997).

We have previously reported the results of a randomized controlled trial of a programme based on the TTM to assist smoking cessation in pregnancy (Lawrence, Aveyard, Evans, & Cheng, 2003). The trial compared standard care with two different programmes based on the TTM, and so far we have reported results concerned only with stopping smoking, confirmed by urinary cotinine measurement. Using intention to treat procedures, we found that there were small differences between the two TTM arms. Combining the two TTM arms, the OR 95% confidence intervals (CI) for stopping smoking at 30 weeks of gestation were 2.09 (0.90–4.85) for 10-week sustained abstinence and 2.92 (1.42–6.03) for point prevalence abstinence relative to controls.

![Figure 1. The staging algorithm (Diclemente et al., 1991).](image-url)
At 10 days after delivery, the OR (95%CI) for quitting were 2.81 (1.11–7.13) and 1.85 (1.00–3.41) for 10-week and point-prevalence abstinence, respectively.

**Hypothesis 1: Did the TTM-based intervention move women through the stages?**

Martin, Velicer, and Fava (1996) proposed that it is preferable to examine the effects of smoking cessation interventions on movement through the stages rather than rely simply on quitting as an outcome measure, because cessation is a rare outcome (and this was certainly true in our trial reported above), while stage movement is more common and theoretically appropriate. Additionally, positive stage movement could lead to future health gain, because, even if women have not stopped smoking in the index pregnancy, they might do so subsequently, benefiting their own health, the health of their child, and the health of a foetus that they might carry in subsequent pregnancies.

Stotts, Diclemente, Carbonari, and Mullen (1996) reported evidence that those pregnant women who stop smoking actually only ‘suspend’ their smoking. Pregnant women who stop smoking do not use the same cognitive and behavioural processes that women and men use who are stopping smoking outside pregnancy. Furthermore, when women have given birth, a larger proportion of women return to smoking, having been abstinent for up to nine months, than would be expected from ‘normal’ quitters (Mullen, Richardson, Quinn, & Ershoff, 1997). Was the approximate doubling of the quit rate observed in our trial brought about because the TTM-based intervention only encouraged women to suspend their smoking behaviour, or did the intervention act as intended and move women through the stages by activating the processes of change? In this paper, we test the hypothesis that the TTM intervention would be more likely to assist women’s movement towards lifetime abstinence from smoking shown by forward movements in stage, or, alternatively, whether the programme encouraged women to greater efforts to suspend their smoking for the duration of pregnancy only, where no stage movements would be expected.

**Hypothesis 2: Does baseline stage moderate the relative effectiveness of the TTM-based intervention?**

Many studies have shown that most smokers are not ready for change; they are in precontemplation or contemplation, with only a minority, under 20%, in preparation (Etter, Perneger, & Ronchi, 1997; Velicer et al., 1995). Prochaska and Velicer (1997) criticized most smoking cessation programmes for not dealing with this. They state that most smoking cessation programmes are orientated towards the 20% in preparation. Consequently, most programmes will not recruit effectively from the 80% who are in earlier stages and, even if they do recruit such people, such programmes will not assist and may actually be counterproductive for people in the earlier stages of change. This is because most programmes encourage the use of processes of change that are appropriate for preparation and action stages, and not appropriate for precontemplation or contemplation stages. Use of the ‘wrong’ process for a particular stage will not help stage movement.

Prochaska, Diclemente, Velicer, and Rossi (1993) and Velicer et al. (1993) describe the development of stage-appropriate recruitment and intervention programmes that will engage all smokers, regardless of their current stage, because they have modules for each of the stages. One hypothesis that flows from this analysis, then, is that stage appropriate materials like those used in Prochaska’s programmes will show large benefits over stage-inappropriate standard materials for those in precontemplation and contemplation. However, the advantage of stage-appropriate materials over standard
materials for those in preparation will be less marked. This is because standard materials, as Prochaska and Velicer (1997) describe, are broadly stage-appropriate for people in preparation. That is, standard materials and TMM-based materials engage and encourage the use of similar processes of change in preparation, but distinctly different processes in the earlier stages. The second hypothesis examined in this paper is that baseline stage will have a moderating effect on the effectiveness of the TTM-based intervention relative to the control intervention (Fig. 2).

The issue of whether stage-matched interventions outperform stage-mismatched interventions has been addressed by two other studies to our knowledge. Dijkstra, De Vries, Roijackers, and Van Breukelen (1998) used a factorial design and produced some evidence that stage-matching was more effective than mismatching in contemplators and preparers. For those in the immotive (precontemplation) stage, however, mismatched interventions were more effective than some matched ones. Quinlan and McCaul (2000) randomly allocated stage-matched and mismatched interventions to 92 college students in precontemplation stage with regard to smoking cessation. The stage-mismatched interventions consisted of preparation/action-orientated advice to do with the process of quitting, while the matched intervention consisted of activities appropriate to precontemplation processes of change, such as considering the myths and facts about smoking. Follow-up 1 month later showed that students in the mismatched intervention were more likely to move stage, and showed stronger intention to quit than students in the matched condition. Thus, there is little evidence for the hypothesis that stage-appropriate materials will be more effective than stage-inappropriate ones.

Method

Recruitment

The methods have previously been reported in detail elsewhere (Lawrence et al., 2003). Briefly, 16 of the 19 midwifery services for the West Midlands agreed to participate in the trial. Midwives deliver antenatal care mainly in community settings rather than hospitals, which means family practice offices. About half of the available family practices were selected to participate, with only one midwife declining. Midwives were asked to attempt to recruit all women aged 16 years and over who declared themselves to be smoking at booking for maternity care (about 12 weeks of gestation). We estimate that they recruited approximately 42% of potentially eligible smokers. Full details on these women’s socio-demographic and smoking habits are published in the trial report (Lawrence et al., 2003). In brief, nearly all were white, almost two-thirds of women had had a baby previously, were of mean (SD) age 26.5 (5.9) years, of average net household income of £100–£200 per week, and, on average, left education aged 16 years.

<table>
<thead>
<tr>
<th>Baseline stage = precontemplation or contemplation</th>
<th>Baseline stage = preparation</th>
</tr>
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<tbody>
<tr>
<td>Intervention appropriate to stage</td>
<td>Relative effectiveness TTM vs. control</td>
</tr>
<tr>
<td>TTM intervention</td>
<td>Appropriate</td>
</tr>
</tbody>
</table>

**Figure 2.** Diagram of hypothesis 2.
Women smoked on average six cigarettes per day at booking, but this increased to 11 cigarettes from mid-pregnancy onward. Two-thirds of women lived with partners that smoked.

**Intervention**

This trial was funded by the National Health Service and was a pragmatic trial (Roland & Torgerson, 1998), in that the intention was to examine whether the TTM-based interventions were more effective than standard care. There was no attempt to control precisely the nature of advice midwives gave women in the control arm, nor did we attempt to control intervention intensity. There were three arms: Arm A, Controls; Arm B, Manuals; and Arm C, Computer. Midwives in each trial arm were aware that they were in one of three trial arms.

The intervention in Arm A was intended to be standard smoking cessation advice given by midwives, who would have variable training and variable skills. Midwives in Arm A received half a day's training on the research protocol only. They were asked to deliver smoking cessation advice as they would normally do. The only attempt to standardize the intervention was that we asked all midwives in this arm to give women the Health Education Authority (of England) leaflet *Thinking about Stopping*. This folded A4 leaflet explains the benefits of stopping smoking for the health of the foetus and gives brief advice on how to stop smoking. This leaflet was given to women that smoked by nearly all midwives anyway. Following this training, midwives were asked to practice recruiting and familiarizing themselves with the trial material. Midwives reconvened for half a day's reflection to check that they were comfortable with the details of the trial protocol and aspects of consent. There were 78 midwives in 32 general practices in this arm. Evidence from one study showed that midwives ask the smoking status of nearly all women, advise most smokers of the risks to their foetus, and two-thirds of smokers receive advice to stop smoking. A minority of smokers receive help to stop smoking and very few are referred on for such help (Cooke, Mattick, & Barclay, 1996).

Midwives in Arms B received 2½ days training. Public Management Associates, who hold the UK licence for the TTM-based interventions, provided 2 days training on the TTM. This consisted of 1½ days training on the concepts of the TTM and familiarization with the stage-based manuals. The research team at the University of Birmingham provided half a day's training on research protocol, as for Arm A. Following this, midwives in this arm practiced recruiting women and using the materials and then had a half-day's reflective session on their experiences and for them to recheck details of the intervention.

Participants recruited to trial Arm B received a set of six professionally-published colour-printed A5 30-page self-help manuals, called the Pro-Change Programme for a Healthy Pregnancy. The set consisted of one manual for each stage of change and a further one for 'recycling'. These manuals explained the concepts of stage of change, helped participants to stage themselves, and contained quizzes and exercises to engage the stage-appropriate processes of change. Additionally, at each of three occasions during pregnancy, booking (fewer than 20 weeks gestation); 23–25 weeks; and at 28–30 weeks, and at 10 days post-partum the midwife assessed a participant’s stage of change, pointed the woman to the appropriate manual in the stage-series with a bookmark and spent no more than 15 minutes ensuring that the participant was familiar with how to use the materials by going through an appropriate exercise with her and discussing it. There were 46 midwives in 30 general practices in this arm.
The midwives in Arm C received the same training as midwives in Arm B. The participants also received the same stage-based self-help manual intervention as Arm B, the midwife staged the woman as in Arm B, and explained how to use the stage-based manuals in the same way. Additionally, these participants used a computer program installed on a laptop computer on each of the four intervention occasions (as in Arm B). Women worked alone without the midwife using the computer program. This consisted of questions to assess a woman’s stage of change. This was followed by on-screen and audio feedback concerning her stage and the meaning of that stage. This format was repeated for the other concepts: decisional balance, temptation, and processes of change, with strategies to help women move stage. This took about 20 minutes to complete. On second and third use, women also received feedback on progress, or lack of it, since the last use. Following each use of the computer, the feedback was printed out and sent to the participant within 1 week of the intervention. There were 51 midwives in 22 general practices in this arm.

Two of us independently coded the self-help interventions of the control and TTM arms to identify which processes of change they were encouraging participants to use. The stage-based manuals were developed by Prochaska and colleagues to encourage the use of processes appropriate for the stage of change. Both raters agreed that the precontemplation manual encouraged the use of consciousness raising and dramatic relief. Contemplation encouraged the use of self re-evaluation, consciousness raising, and environmental re-evaluation. Preparation encouraged the use of self liberation, stimulus control, contingency management, and helping relationships. According to a recent description of the theory, these processes are matched to stage (Prochaska & Velicer, 1997). The leaflet given to the control arm patients, however, predominantly focused on self-liberation, helping relationships, counter conditioning, stimulus control, and contingency management, the processes of which are appropriate for the preparation and action stages. This leaflet was an abbreviated version of the advice in the preparation manual. The leaflet also covered issues such as why smoking in pregnancy is harmful – aimed at causing the use of consciousness raising and dramatic relief, which is appropriate for those in precontemplation. However, the leaflet was dominated by advice on how to quit and therefore most appropriately matched for those in preparation and mismatched for those in precontemplation and contemplation.

**Allocation**

Midwifery teams in each general practice were allocated by a computerized minimization algorithm that balanced the characteristics of the population registered with each general practice across arms of the trial. These characteristics were the Townsend score (a measure of the material deprivation of the population served by the general practice; four groups), urban/rural location (two groups), and birth rate (three groups).

**Data collection and outcome assessment**

Women recorded their stage of change and other data at each of the four trial contact points, booking, 20–23 weeks, 28–30 weeks, and 10 days post-partum using a self-completion questionnaire handed to them by their midwife. This was completed by the woman at home and then posted back to the researchers. Women in Arm C completed their staging questionnaire on computer because it comprised part of the intervention. The questions were identical, using the algorithm defined by Diclemente et al. (1991). For some women in Arm C, midwives did not administer the computer
intervention and thus the staging questionnaire at the booking interview. In such cases, if the questionnaire was deferred for more than 2 weeks, we set stage to missing; hence there are more women with missing stage in Arm C. Deferment of intervention appeared random with respect to stage recorded when the intervention/questionnaire was delivered, or the other characteristics of the women, so would not be expected to cloud the results.

Two outcome measures were used in this report: movement in stage of change and smoking cessation. Stage was defined according to the algorithm described by Diclemente et al. (1991). The two smoking cessation outcomes were self-reported point prevalence of smoking cessation and 10-week sustained abstinence assessed at 30 weeks and 10 days post-partum. Self-reported point prevalence smoking cessation was defined by responses to the question ‘How many cigarettes do you normally smoke in a day?’ where one of the multiple-choice responses ‘I have given up’ was expected. Additionally, women had to have smoked no cigarettes in the past 24 hours and to have reported consistent smoking status on the staging questions included in a second questionnaire completed at the same time. For 10-week continuous abstinence, women had to report in addition to the above that they had not smoked any cigarettes in the past 10 weeks.

The change in stage between baseline and outcome measured at 30 weeks of gestation and again at 10 days post-partum was examined in two ways. First, we classified women as having made a positive movement in stage or not on the basis of whether they had moved from their baseline starting stage to a stage that was closer to quitting smoking. Second, we calculated a change score. A positive move from stage at baseline to the adjacent stage at follow-up was counted as plus one, a negative movement to an adjacent stage as minus one, and a move to the next but one stage as two, and so on.

Did the TTM-based intervention move women through the stages?

We accounted for the randomization of family practices and not individuals by random effects regression, using Multi-level Modelling for Windows (MLwiN), treating family practice as a random effect. For the categorical variable of positive stage movement/no positive stage movement, we used logistic regression, and for the change score we used linear regression. The effects of trial arm were assessed by a $\chi^2$ test in these regression models. We then adjusted for baseline characteristics of women: daily cigarette consumption, Fagerstrom test for nicotine dependence (Heatherton, Kozlowski, Frecker, & Fagerstrom, 1991), having a partner, having a partner that smoked, baseline stage, family net income, educational level, age, and ethnic group. Women who were followed up but whose change in stage or smoking status was missing were excluded from the analyses. However, we conducted sensitivity analysis by including these women and classifying them as not having made a positive change and by giving such women the mean score for their arm. Further, we did this for all baseline recruits even if they subsequently dropped out or were not followed up. However, these results were not different to those obtained only on those with complete data and so are not reported.

Does baseline stage moderate the relative effectiveness of the TTM-based intervention?

The hypothesis was that the effectiveness of the TTM-based materials would be most marked for those in the earliest stages of change. For this, we used two smoking cessation outcomes and the two stage movement outcomes. These were: 24-hour point...
prevalence abstinence and 10-week continuous abstinence, and positive movement in stage and stage score. All outcomes were examined at both 30 weeks of gestation and 10 days post-partum. For these analyses, we created multiplicative interaction terms between baseline stage and trial arm. We tested whether inclusion of the interaction term in the regression models described above was statistically significant with a \( \chi^2 \) test. In these analyses, we conflated precontemplation and contemplation stages and the two TTM arms for three reasons. First, the processes of change needed to move from precontemplation to contemplation and from contemplation to preparation are similar, but different from those needed to move from preparation to action (Prochaska & Velicer, 1997). Hence the effect of stage mismatching of the standard intervention on women in precontemplation and contemplation would be expected to be similar. Second, conflating the groups in this way maximizes the power to detect any interaction effect. Third, both TTM interventions were stage-matched, while the control intervention was not.

Results
In total, 918 women entered the study, 289 in Arm A, 305 in Arm B, and 324 in Arm C. The baseline characteristics of both midwives and women did not differ greatly by arm (Lawrence et al., 2003). At 30 weeks of gestation, 186 women had withdrawn from the study, and by 10 days post-partum, 207 women had done so, mainly because of an early end to their pregnancy, or changing general practice. Rates of withdrawal and reasons for withdrawal did not differ by trial arm. Additionally, 88 women did not complete either of their two scheduled questionnaires at 30 weeks, and 58 women did not do so at 10 days post-partum. Some women completed one questionnaire but not the other, and in some the data were incomplete or contradictory so that smoking status could not be assigned to 34 women at 30 weeks gestation and 7 women at 10 days post-partum. Similarly, stage of change could not be assigned to 73 women at 30 weeks, and 50 women at 10 days post-partum. Women with absent data were excluded as described above. There were, however, few differences between the characteristics of women for whom data were complete and those women who joined the study and either dropped out, or in whom data was missing. The two groups had similar and not significantly different baseline smoking habits, baseline cotinine levels, mean scores on the Fagerstrom Test for Nicotine Dependence, stage of change, age, ethnicity, parity, proportion having a partner, proportion whose partner smoked, and gestational age at booking. There were, however, statistically significant differences in the educational level and income of those with complete data and those with missing data. Those with missing data were significantly less well educated, with 34.0% of women with missing data having no educational qualifications compared with 23.7% of women with complete data. Similarly, 59.5% of women with missing data had a net household income of less than £200 per week, compared with 45.8% of women with complete data.

The baseline stage distribution is shown in Table 1, and it shows that more women in Arm C were recorded as having missing stage data, for the reason described above. Excluding women with missing stage, there was no significant difference in the distribution of women between stages at baseline between trial arms.

Did the TTM-based intervention move women through the stages?
At 30 weeks of gestation and at 10 days post-partum, women in the TTM arms were statistically more likely to make positive stage movements (Table 2). Women in Arm C were more likely than women in Arm B to make such changes, and the point estimate
shows that the effect size was small. Women in Arm C were approximately 60% more
likely to have made a positive stage movement than women in Arm A. Adjustment for
differences between arms in the characteristics of women only strengthened this effect.
When combined together, the unadjusted OR (95% CI) for positive change in the
TTM-based arms (Arms B and C) versus Arm A was 1.65 (1.14–2.39) at 30 weeks and
1.39 (0.97–1.98) at 10 days post-partum.

The same clear pattern of a benefit for those in the TTM arms was not, however, seen
with the outcome of change score (Table 3). (The change score was the difference in
number of stages between starting and ending stage). There were only small differences
in means between the groups. Arm C had a clear but not statistically significant benefit
over A, but for B, this advantage over Arm A was less clear. However, adjustment for the
characteristics of women in each arm made the benefit of the TTM arms clearer, and
there was a statistically significant difference between the arms at 10 days post-partum.
When combined together, the mean unadjusted difference (95% CI) in change score for
Arms B and C minus Arm A was 0.09 (−0.07 to 0.25) at 30 weeks gestation, and at
10 days post-partum it was 0.03 (−0.14 to 0.20).

**Does baseline stage moderate the relative effectiveness of the TTM-based
intervention?**

There was no evidence that the relative benefit over Arm A of the combined arms of B
and C, labelled TTM, was greater for women in precontemplation and contemplation
than for women in preparation (Tables 4 and 5). In all eight outcomes examined, the
relative benefit of the TTM-based intervention was greater in preparation, although in
no case was the test for interaction statistically significant. Contrary to the hypothesis,
then, the relative benefit of the intervention was not greater for women in
precontemplation and contemplation.

**Discussion**

Women in the TTM arms were more likely to make positive movements in stage. This is
evidence that the effect of the TTM intervention on smoking occurred because women
changed their intention to smoke in the medium term, rather than simply, as (Stotts
et al., 1996) term it, suspend their smoking behaviour. This evidence is in favour of the
validity of the TTM, but this evidence provides only weak support for the validity of the
model. This pragmatic trial was designed to show primarily whether these
TTM packages outperformed standard care, so there was no attempt to make standard
care as intensive as the intervention arms. In other words, we did not control for dose,
thus women changing their intention provides limited support for the TTM, though
Table 2. The effect of the TTM intervention relative to the control on positive change in stage

<table>
<thead>
<tr>
<th></th>
<th>Unadjusted</th>
<th>Adjusted</th>
<th>Test for difference between arms</th>
<th>Test for difference between arms</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Arm A</td>
<td>Arm B</td>
<td>Arm C</td>
<td>%</td>
</tr>
<tr>
<td>Positive movement in stage at 30 weeks gestation</td>
<td>23.0%</td>
<td>30.3%</td>
<td>1.45 (0.88–2.40)</td>
<td>37.6%</td>
</tr>
<tr>
<td>Positive movement in stage at 10 days post-partum</td>
<td>24.9%</td>
<td>24.9%</td>
<td>1.00 (0.60–1.68)</td>
<td>38.7%</td>
</tr>
</tbody>
</table>
Table 3. The effect of the TTM intervention relative to the control on change in stage score between baseline and follow-up

<table>
<thead>
<tr>
<th>Stage match/mismatch interventions</th>
<th>Unadjusted</th>
<th>Adjusted</th>
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</thead>
<tbody>
<tr>
<td>Mean (95%CI) A</td>
<td>Mean (95%CI) B</td>
<td>Mean (95%CI) C</td>
</tr>
<tr>
<td>Difference (95%CI) B-A</td>
<td>Difference (95%CI) C-A</td>
<td>Test for difference between arms</td>
</tr>
<tr>
<td>x^2, p</td>
<td>x^2, p</td>
<td></td>
</tr>
</tbody>
</table>

Change in stage score at 30 weeks gestation

<table>
<thead>
<tr>
<th>Arm A</th>
<th>Arm B</th>
<th>Arm C</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.07</td>
<td>0.12</td>
<td>0.05</td>
</tr>
<tr>
<td>(0.05–0.17–0.27)</td>
<td>(0.21–0.14–0.09–0.36)</td>
<td>(0.12–0.07–0.03)</td>
</tr>
<tr>
<td>1.45, 0.49</td>
<td>0.22 (0.001–0.43)</td>
<td></td>
</tr>
<tr>
<td>4.41, 0.11</td>
<td></td>
<td></td>
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</tbody>
</table>

Change in stage score at 10 days post-partum

<table>
<thead>
<tr>
<th>Arm A</th>
<th>Arm B</th>
<th>Arm C</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.02</td>
<td>0.08</td>
<td>0.10</td>
</tr>
<tr>
<td>(0.08–0.34–0.14)</td>
<td>(0.19–0.08–0.41)</td>
<td>(0.03–0.20–0.25)</td>
</tr>
<tr>
<td>4.81, 0.09</td>
<td>0.30 (0.05–0.55)</td>
<td></td>
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<tr>
<td>6.72, 0.035</td>
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Table 4. Is the effect of the TTM intervention relatively greater on women in precontemplation and contemplation stages compared with women in the preparation stage? Dichotomous outcomes

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Precontemplation/Contemplation</th>
<th>Preparation</th>
<th>Significance of interaction term</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>% Control</td>
<td>% TTM</td>
<td>OR TTM vs. Control</td>
</tr>
<tr>
<td>Point prevalence of quitting at 30 weeks of gestation</td>
<td>6.4%</td>
<td>4.7%</td>
<td>0.71</td>
</tr>
<tr>
<td>10 weeks abstinence at 30 weeks of gestation</td>
<td>4.4%</td>
<td>2.3%</td>
<td>0.51</td>
</tr>
<tr>
<td>Positive movement in stage at 30 weeks gestation</td>
<td>26.9%</td>
<td>36.6%</td>
<td>1.57</td>
</tr>
<tr>
<td>Point prevalence of quitting at 10 days post-partum</td>
<td>9.2%</td>
<td>8.7%</td>
<td>0.94</td>
</tr>
<tr>
<td>10 weeks abstinence at 10 days post-partum</td>
<td>4.3%</td>
<td>3.1%</td>
<td>0.70</td>
</tr>
<tr>
<td>Positive movement in stage at 10 days post-partum</td>
<td>26.3%</td>
<td>31.0%</td>
<td>1.25</td>
</tr>
</tbody>
</table>
it does provide encouragement that intensive interventions help women move on in their thinking about smoking, even if they do not quit. It also supports the evidence for efficacy of the intervention seen in the previously reported findings of a small and borderline significant relative benefit for the smoking cessation outcomes (Lawrence et al., 2003).

The benefit of the TTM interventions in producing positive stage movements was less clear when stage movement was treated as a score, rather than as a dichotomous variable (positive movement or not). When we examined this more closely, this occurred because women that made a positive movement in the control arm had a mean change score that was 0.30 points higher than women making a positive movement in the TTM arms. An alternative explanation for this would have been that women who made backward movements had larger negative scores in the TTM arms than in the control arm. This was not the case with the mean change score being 2.12 in such women in the control arm and 2.19 in such women in the TTM arms. The significance and cause of this greater positive movement in the control arm is unclear and this is a post hoc finding and must be treated with caution.

A more rigorous and specific test of the TTM was provided by the second hypothesis. That is, stage-based interventions would be particularly useful for women in precontemplation and contemplation, whereas standard interventions would leave such women unmoved. In contrast, standard interventions would be relatively more effective for women in preparation because such interventions are unintentionally stage-matched. Instead, the evidence suggested that the stage-based materials particularly helped women in preparation compared with the standard materials. The validity of our second test, that the effects of the TTM model would be most marked in precontemplation and contemplation, depends upon the relative similarity of the control and TTM-based interventions for women in preparation, and the dissimilarity of the interventions for women in precontemplation and contemplation. We described in the method our assessment of process use relating to stage of change. Both the preparation manual and the leaflet predominantly gave what we consider to be standard advice on how to stop smoking (Raw, 2000). The precontemplation and contemplation manuals were very different to this, and, according to the TTM, were matched to stage. Thus our study provides a valid test of this hypothesis.
Where do these conclusions leave the TTM? The intervention seems to have worked. More women stopped smoking and more women moved stage towards quitting. However, the results concerning stage-appropriate interventions raise the question of whether it is engaging the stage-appropriate processes that has led to this success. These results are partly consistent with those of Dijkstra et al. (1998) and agree with those of Quinlan and McCaul (2000), discussed in the Introduction. We found, that the TTM-based intervention was, if anything, relatively more effective than the standard intervention for women in preparation, when both interventions were stage appropriate. This replicates an unheralded finding from Prochaska et al.'s (1993) trial. As in our trial, the stage-matched interventions in Prochaska trial were also more intensive than the stage-mismatched intervention. Likewise, the stage-matched interventions were of greater benefit relative to the control intervention for people in preparation than for people in either precontemplation or contemplation. One interpretation of these findings, therefore, is that people in preparation respond more favourably to intensive interventions because they are primed and interested to do so. In other words, the benefit of the TTM-based interventions seen in these two trials may simply arise because more intensive support was given to people ready to quit.

There are other interpretations of these findings. One possibility is that the packaging of the intervention was responsible for these results. That is, perhaps if the intervention were re-formulated, it might be that the stage-based intervention would be more effective than the control intervention for those in precontemplation and contemplation. A second interpretation is that the staging algorithm is inadequate generally, and it has certainly been extensively criticized on both logical and pragmatic grounds (Etter & Sutton, 2002; Litell & Girvin, 2002; Sutton, 1999). The staging algorithm might be especially inaccurate for pregnant women. Stotts, Diclemente, Carbonari, and Mullen (2000) have suggested that pregnant women should be staged in a different way than using the algorithm that we used. They propose that their method captures the special nature of pregnant women’s intention to quit smoking more appropriately. If this algorithm is more appropriate than the standard algorithm, then we may have applied mismatched interventions to many women and might have created the effect we observed.

Most pregnant smokers adjust their smoking behaviour in pregnancy (Owen et al., 1998). One interpretation of the moderately large proportion of women making positive stage movements and the relative benefit of the TTM-based interventions in assisting this is that this majority are primed to take action, and benefited from the extensive planning for quitting information in the preparation manual. (All women received the manual for every stage of change). On this analysis, the movement in stage could be explained partly by increased quitting behaviour, which of necessity indicates positive stage movement, and by increased confidence in their ability to quit expressing itself as more definite intention, which also creates positive stage movement. Only long-term follow-up will show whether these women’s positive stage movements were the beginnings of a journey to long-term quitting, or were reflecting an increased confidence in their ability to temporarily suspend their smoking.

This study suffered from limitations in addition to not controlling for the intensity of intervention. First, the women included in the study were a minority of all potential women available. However, this should not bias the results against the TTM because assignment to the arms was then randomized. Second, data were incomplete through loss to follow-up or failure of midwives to distribute questionnaires and failure of women to complete all questionnaires at the appropriate times. Incomplete data...
appeared to be largely missing completely at random, though there was some evidence of systematic loss. However, sensitivity analysis with all women included in the data with assumptions about their status did not change the results.

In summary, the advantage of the TTM-based interventions in smoking cessation and change in stage is consistent with the TTM being a valid model of smoking cessation in pregnancy, but this is a weak test of the validity of the TTM. Furthermore, the failure to confirm the more specific hypothesis derived from the TTM casts doubt as to whether the TTM represents a valid model of smoking cessation in pregnancy.

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References


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