Paper:
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Randomised control trial of the impact of a brief tele-support intervention on initial attendance at physiotherapy group sessions for pelvic floor problems

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Short title: Tele-support.

Abstract

OBJECTIVE: To assess the efficacy of a brief telephone call to patients on a waiting list for physiotherapy treatment for pelvic floor dysfunction on initial attendance.

DESIGN: A three-armed randomized control study.

SETTING: An outpatient physiotherapy clinic at a hospital.

PARTICIPANTS: 130 consecutively referred women patients (mean age of 51.47, range = 26-84) with a variety of pelvic floor dysfunction problems.

INTERVENTION: Support phone call (2 to 10 min) 3 days prior or 3-days after receiving an appointment invitation letter to physiotherapy sessions.

MAIN OUTCOME MEASURES: Attendance at the initial physiotherapy group session.

RESULTS: Groups receiving a phone call demonstrated 80% attendance at the session, with no significant difference between these groups. The group receiving no call had significantly lower attendance rates (50%) than the phone call groups. The telephone support was more effective for those people who were older, came from less economically deprived areas, and had been on the waiting list for less time.

CONCLUSION: Brief tele-support may be an effective method to enhance patient attendance at treatment, but it may work best when targeted at certain groups of individuals.

KEYWORDS: brief tele-support; patient-compliance; pelvic floor dysfunction; effectiveness predictors; attendance physiotherapy.

ABBREVIATIONS: N/A.
Pelvic floor dysfunction affects around 25% of adult females\(^1,2\), and this can rise to 50-60% in women who have experienced child birth\(^3\) or who are over 60 years of age\(^4\). Physiotherapy treatment for female pelvic floor dysfunction can be effective\(^5,6\), and is also safe, acceptable, and has a relatively low cost\(^7\). Partly as a result of being recommended as first-line treatment for many pelvic floor problems\(^7\), time on waiting list for physiotherapy are increasing, and can now be up to 30 weeks\(^8\).

Waiting times are a key issue and performance indicator for publically-funded health services\(^9-11\), and are implicated in the effectiveness of physiotherapy interventions\(^12-14\). The negative impacts of waiting times on patients, staff, and treatment outcomes, are well documented\(^12-14\); and the longer the waiting time, the more likely patients are not to attend scheduled treatment\(^13,15\). Clearly, the success of the physiotherapy relies on attendance at scheduled appointments and compliance with the treatment regime\(^16\). Given this, non-attendance is potentially damaging to patient recovery, and can be financially costly, as patients not receiving physiotherapy could eventually undergo surgical interventions which are more expensive than physiotherapy treatment.

The use of various forms of appointment reminders for patients has been studied\(^15,17-19\), but many currently employed forms of reminder present problems for a population with pelvic floor dysfunction. Reminders sent through electronic devices, such as text and SMS, are cheap and effective\(^15,19\), but they may not work well with a population who can be older\(^20\), which is the case for many patients referred for urinary incontinence\(^4\). Phone reminder-messages can work\(^15,17-18\), but they are not as effective for those with associated mental health problems or poor socio-economic situations\(^21\), and it should be noted that around 50%-60% of women with incontinence display depression and/or anxiety problems\(^16,22\).

Given these considerations, the current study examined the efficacy of a novel brief tele-support intervention on initial attendance for patients on a waiting list for physiotherapy
treatment for pelvic floor dysfunction. The intervention was telephone based, but involved a slightly longer interaction than just the brief reminders examined previously. The study also examined whether there was an optimal target population, and time spent on waiting list, to which to deliver the tele-support intervention; factors that previously have not been explored. To this end, a range of previously-implicated patient characteristics, such as age, time on waiting list, and economic deprivation were studied as factors that might impact on attendance and the effectiveness of the tele-support intervention.

Method

Ethics Statement

Ethical approval was granted to this study by the NRES Committee Region - East Midlands, UK. The trial is registered on clinicaltrials.gov (NCT02563600).

Participants

One hundred and thirty consecutively-referred female patients on a waiting list for physiotherapy group sessions for pelvic floor problems, at an outpatient physiotherapy clinic in a hospital in Wales, were approached at the time of their referral and asked if they would participate in research relating to the success of physiotherapy programmes for their condition. Of those participants approached, 128 agreed to participate by signing a consent form. The inclusion criteria were that the women be referred to the service for a pelvic floor dysfunction (i.e. stress incontinence, urge incontinence, prolapse, or some combination of these problems, and had to be over 18 years of age. Women were excluded if they were referred for third degree perineal tears.

The participants were randomly assigned to one of three groups according to an electronically-generated random number between 1 and 3 (using the SPSS v22 statistical
programme). This randomization was conducted by the senior author (who was blind to the characteristics and demographics of the participants: No call group \(n = 44\); Pre-appointment-letter call group \(n = 52\); Post-appointment-call group \(n = 32\). It should be noted that 5 participants who had originally been assigned to the pre-letter call group ended up in the post-letter call group due to problems contacting these patients, but no participants assigned to either call group ended up in the no call group. Nevertheless, an intention to treat approach to the analyses was adopted, so that the analyses had patients in the treatment group that they were randomized to, regardless of whether or not they received the intervention (see Figure 1 for details of the allocation).

Power calculations regarding the number of participants required to detect a difference in terms of attendance using a chi-square analysis, had revealed that 108 patients would be required to have an 80% chance of detecting significance at the 5% level for a medium effect size (i.e. \(r = 0.30\)) when three groups were used in the analysis\(^{23}\). It was also planned to determine if any of the patient demographic characteristics would impact attendance using logistic regression, and power analysis revealed that, for a medium effect size \(\left(\Gamma = 0.15\right)\), using a significant criterion of 5% with 80% power, then 54 participants would be need when 1 predictor was used, and 84 participants would be needed with 4 predictors.

**Support Call**

The telephone support call was delivered by a psychologist, and took the form of a semi-structured discussion that consisted of six components that were delivered in the
following order: (1) an initial brief introduction specifying who the caller was (a psychologist working in the physiotherapy department of the hospital where they were to be treated) ; (2) where they were from (the hospital); (3) the purpose of the call (to give the patient some details about their appointment and their treatment, and allow the patient to ask any questions that they may have); (4) the details of the patient’s first appointment time (day, time, location); (5) an outline of the physiotherapy treatment and its potential benefits (detailing the number of sessions of treatment, outlining the kinds of things that would be learned about and discussed in the sessions, approximately how often the sessions would occur, and a brief account of the objectives of this treatment and what benefits it might offer – also noting that not everybody shows these improvements); and (6) a chance for the patient to ask questions.

The telephone call lasted an average of 5min (usual range 2 – 10min), although a small number of calls lasted between 15–20min). The telephone calls were made to a landline number whenever possible (to reduce cost), and they were usually made between 3.00pm and 6.30pm (to optimise chances of contact with the patient). The telephone calls were made around 3 days before (pre), or 3 days after (post), the invitation letter was received, which was sent about 4 weeks pre-appointment.

Procedure

The No call group (n = 44) received the standard invitation letter about two weeks prior to their appointment but did not receive a telephone call. The pre-letter group (n = 52) received the telephone call support 2-3 days prior to their invitation letter. The post-letter group (n = 32) received the telephone call 2-3 days after their invitation letter. The primary outcome measure to be taken was attendance or non-attendance at the initial session of the PFMT programme. These attendance data were taken by the physiotherapist running the class, who was blind to the group assignment of the patient.
Results

The 130 women participants had a mean age of 51.47 (± 13.33; range = 26–84) years, and a mean BMI of 29.56 (± 7.14; range = 20–63). The participants had been referred for a variety of pelvic floor problems: 12.5% stress urinary incontinence but no prolapse; 3.1% urge urinary incontinence but no prolapse; 38.3% mixed urinary incontinence but no prolapse; 0.8% faecal incontinence but no prolapse; 18.2% prolapse; and 27.3% mixed incontinence and prolapse. The index of deprivation was calculated using the Welsh Index of Multiple Deprivation (WIMD), which is the official measure of relative deprivation for areas in Wales. It is designed to identify small areas where there are the highest concentrations of several different types of deprivation (income, employment, health, education, access to services, community safety, physical environment, and housing), and codes deprivation levels of the postcode area from 1 = most deprived to 5 = least deprived: 11.4% were from area 1; 13.3% from area 2; 2.9% from area 3; 19% from area 4; and 53.3% from area 5. The mean waiting time from the letter referring the patient to the service to the letter inviting them to attend physiotherapy group sessions was 19.41 (± 11.19; range = 1–43) weeks. The demographic detail of each of the three groups is shown in Table 1.

Table 1 about here

Figure 2 about here

The number of patients who attended their initial physiotherapy session for each group was calculated, and the percentages are shown in Figure 2. Inspection of these data
suggests that around 50% of patients who did not receive a telephone call attended their initial group session. In contrast, about 80% of the pre-letter call and post-letter call patients attended. These data were analysed by chi-squared that revealed a statistically significant difference in levels of attendance between the groups, $X^2(2) = 10.51, p < 0.01; r = 0.284, 95\% CI = 0.115 – 0.437$. Follow-up tests revealed that the two groups receiving a support call (when grouped together) had significantly higher attendance rates than the no call group, $X^2(1) = 10.45, p < 0.01; r = 0.339, 95\% CI = 0.138-0.513$, but the two telephone call groups did not differ statistically from one another, $chi square < 1$.

Table 2 about here

Table 2 shows Spearman’s correlations for the sample between predictor variables (age, BMI, time on waiting list, and deprivation area) and attendance at the initial session. There were very few statistically significant relationships: the greater the patient age the greater the deprivation level (indexed by a low WIMD score), and the greater deprivation area the greater the BMI. Although patient age, time on waiting list, and deprivation area, all had relationships with attendance of $p < .08$, none of these correlations was statistically reliable. A logistic regression with attendance as the dependent variable and the demographic characteristics (age, BMI, deprivation, and waiting time) as predictors was conducted, and revealed that, while the model containing the four predictors did significantly predict attendance, -$2LL = 0.00, X^2(4) = 10.45, p < .05$, none of the individual variables were independently significant predictors of attendance.
Figure 3 displays the percentage of patients who attended the initial physiotherapy session depending on whether they received a phone call (both groups combined) or did not receive a call, split by their demographic characteristics. The left panel displays the results for the sample split at the sample-mean for age. The phone call tended to elevate levels of attendance to a greater extent in the older group (52+ years) than for the younger group: there was a 40% elevation above the no call group for the younger group, and a 50% elevation for the older group. A logistic regression conducted for the lower age group revealed no statistically reliable impact of receiving a call on attendance, $-2LL = 75.79, X^2 = 2.76, p > .10$. There was a significant impact of receiving a call for the higher age group, $-2LL = 65.54, X^2 = 5.11, p < .05$, with the odds ratio of receiving a phone call increasing attendance being = .251.

The second left panel displays the results for the sample split at the sample-mean for BMI. There was little differential impact of the phone call on attendance for lower (< 30) or higher (30+) BMI scorers. Logistic regressions conducted for both the lower and higher BMI groups failed to reveal reliable impacts, both $ps > .40$.

The second from the right panel displays the results for the sample split at the sample-mean for time on the waiting list. The phone call tended to elevate levels of attendance to a greater extent in the shorter waiting list group (less than 20 weeks) than for the longer waiting list group: there was a 35% elevation above the no call group for the younger group, and a 47% elevation for the older group. A logistic regression revealed a reliable impact of receiving a call on attendance for the shorter waiting time group, $-2LL = 50.27, X^2 = 6.99, p > .10$, with the odds ratio of receiving a phone call increasing attendance being = .170. There was no significant impact of receiving a call for the longer waiting list group, $-2LL = 78.00, X^2 = 2.23, p > .10$. 
The right panel displays the results for the sample split into lower deprivation (areas 3, 4, and 5) and higher deprivation (areas 1 and 2). The phone call elevated attendance to a greater extent in less deprived areas: there was a 35% elevation above the no call group for the more deprived areas, but a 52% elevation for the less deprived areas. A logistic regression conducted for the less deprived areas revealed a reliable impact of receiving a call on attendance, $-2LL = 63.42, \chi^2 = 7.93, p < .01$, with the odds ratio of receiving a phone call increasing attendance being $= .184$. There was no significant impact of receiving a call for the longer waiting list group, $-2LL = 34.25, \chi^2 = 1.17, p > .20$.

**Discussion**

The telephone support call to patients on a waiting list for physiotherapy group sessions improved attendance by approximately 30 percentage points relative to patients who did not receive such a phone call. The timing of the phone call relative to the invitation letter (at least within the time frame studied here) did not make a difference to initial attendance. These data show the utility of a brief support phone call on increasing attendance at scheduled treatment, and replicate the effectiveness of similar interventions in other areas\textsuperscript{15,17,18}. However, the impact on attendance of the brief tele-support call was greater in the current study than the impact of the simple tele-reminders seen in previous studies\textsuperscript{15}.

A number of factors that impacted the effectiveness of the tele-support were noted. The tele-support call was more effective for those patients who were older, had been waiting less long for their appointment, and who came from less deprived areas. While it has previously been noted that such reminders work better for those from less deprived areas\textsuperscript{21}, the other findings regrading predictors of success are novel. It may be that the use of a telephone call as a support device works better than text or SMs reminders for older people due to their familiarity with this technology\textsuperscript{20}. It might also be noted that these factors: being
older\textsuperscript{15}, waiting less time for an appointment\textsuperscript{13}, and being less economically deprived\textsuperscript{21}, have previously been associated with increased likelihoods of attendance. These trends were numerically but not statistically noted in the current study. These considerations suggest that the phone call may serve to bolster the patients’ intentions with regard to treatment, further enhancing the likelihood that these patients will attend the session.

A number of limitations with the study should also be considered in extrapolating from the current results. For example, a psychologist made the support call, and it is unclear if this had any impact on the outcomes. It would be hoped that such an approach could be generalised to any health professional working in this area, and there was nothing particularly psychological in the content of the support call, which would suggest that the findings could be replicated. However, inter-personal skills would clearly be important in this context, and this issue needs to be addressed. The study was conducted in Wales, which has some implications for its generalizability. For example, waiting list times may vary from this country to other countries, and the degree of generalisation to developing countries would also need to be established. Finally, it was not possible to know whether the participants had received physiotherapy treatment previously, which may have had an impact on the outcome.

Nevertheless, the tele-support was generally effective, if less so for patients who are younger, more economically deprived, and had been waiting longer, to the same extent. Given this, it may well be necessary to consider a wide range of factors in enhancing attendance at treatment; controversially, it may be that the economic area within which a service operates might be taken as a guide to the types of investment that may be most beneficial for the service. For example, in more affluent areas, where staffing is good, and waiting lists are shorter, then psychological supports, including tele-support, may well be the most cost-effective use of resources to bolster attendance\textsuperscript{16} and help promote treatment outcome\textsuperscript{13,15}. However, in more deprived areas, where staffing is stretched, and waiting lists
are longer, it may be that investment in physiotherapists to reduce the waiting times would be most beneficial. These suggestions are clearly speculative, but highlight the complexity of attempting to engage patients with their treatment, and show that different approaches may well be needed with different populations to optimise the outcomes.
References


18. Gurol-Urganci I, de Jongh T, Vodopivec-Jamsek V, Atun R, Car J. Mobile phone messaging reminders for attendance at healthcare appointments, *status and date: New*
search for studies and content updated (no change to conclusions) published in (12).

2013.


FIGURE CAPTIONS

Figure 1: CONSORT diagram showing the flow of participants through each stage of a randomised trial.

Figure 2: Percentage of patients attending the first appointment of the physiotherapy intervention. Pre-letter call = patients receiving call prior to their invitation letter; Post-letter call = patients receiving call after their invitation letter; No call = patients receiving no telephone call.

Figure 3: Percentage of patients attending who did or did not receive a telephone call, split by lower or higher age, BMI, waiting list time, and economic-social deprivation.
Figure 1: CONSORT diagram showing the flow of participants through each stage of a randomized trial.

- **Assessed for eligibility** (n = 128)
  - Excluded (n = 0)

- **Randomized (n = 128)**
  - **Allocated to pre-letter group** (n = 52)
    - Received allocated intervention (n = 47)
    - Did not receive allocated intervention
  - **Allocated to post-letter group** (n = 32)
    - Received allocated intervention (n = 37) (5 participants allocated to pre-letter group were actually post-letter)
  - **Allocated to no intervention group** (n = 44)
    - Received allocated intervention (n = 44)
    - Did not receive allocated intervention

- **Follow up**
  - Lost to follow up (n = 0)
  - Lost to follow up (n = 0)
  - Lost to follow up (n = 0)

- **Analyzed**
  - Analyzed (n = 47)
    - Excluded from analysis (n = 0)
  - Analyzed (n = 37)
    - Excluded from analysis (n = 0)
  - Analyzed (n = 44)
    - Excluded from analysis (n = 0)
Figure 2. Percentage of patients attending the first appointment of the physiotherapy intervention. Pre-letter call = patients receiving call prior to their invitation letter; Post-letter call = patients receiving call after their invitation letter; No call = patients receiving no telephone call.
Figure 3: Percentage of patients attending who did or did not receive a phone call, split by lower or higher age, BMI, waiting list time, and deprivation.
Table 1: Top panel = Characteristics (mean, standard deviation, range) of the three groups (top panel). Bottom panel = diagnosis in terms of percentage (and number) of participants in group.

<table>
<thead>
<tr>
<th></th>
<th>No call</th>
<th>Pre-call</th>
<th>Post-call</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>45.44 (14.19)</td>
<td>51.13 (13.44)</td>
<td>53.38 (10.72)</td>
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<tr>
<td>BMI (kg/m²)</td>
<td>31.33 (6.67)</td>
<td>28.41 (5.60)</td>
<td>28.67 (8.95)</td>
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<td>Waiting Time (weeks)</td>
<td>21.02 (10.00)</td>
<td>21.13 (12.73)</td>
<td>22.53 (11.06)</td>
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<td>Deprivation Area (WIMD)</td>
<td>3.59 (1.92)</td>
<td>3.88 (1.49)</td>
<td>4.23 (1.33)</td>
</tr>
<tr>
<td>Time to letter (weeks)</td>
<td>18.98 (10.07)</td>
<td>19.04 (12.69)</td>
<td>20.53 (10.26)</td>
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</tbody>
</table>

<table>
<thead>
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<th>No call</th>
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<th>Post-call</th>
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<tbody>
<tr>
<td>Stress Incontinence</td>
<td>20.4% (9)</td>
<td>7.7% (4)</td>
<td>9.4% (3)</td>
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<tr>
<td>Urge Incontinence</td>
<td>0% (0)</td>
<td>3.9% (2)</td>
<td>6.3% (2)</td>
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<tr>
<td>Mixed Incontinence</td>
<td>31.8% (14)</td>
<td>42.3% (22)</td>
<td>40.6% (13)</td>
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<tr>
<td>Faecal Incontinence</td>
<td>2.7% (1)</td>
<td>0% (0)</td>
<td>0% (0)</td>
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<tr>
<td>Prolapse</td>
<td>18.2% (8)</td>
<td>19.2% (10)</td>
<td>15.6% (5)</td>
</tr>
<tr>
<td>Prolapse &amp; Mixed Incont</td>
<td>27.3% (12)</td>
<td>26.9% (14)</td>
<td>28.1% (9)</td>
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Table 2: Spearman correlation’s (and probability) between the patients’ demographic characteristics and attendance at initial physiotherapy session.

<table>
<thead>
<tr>
<th></th>
<th>Attendance</th>
<th>BMI</th>
<th>Waiting Time</th>
<th>Deprivation</th>
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<tbody>
<tr>
<td>Age</td>
<td>.155 (.08)</td>
<td>-.071 (.53)</td>
<td>-.009 (.92)</td>
<td>.187 (.02)</td>
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<tr>
<td>BMI</td>
<td>-.144 (.20)</td>
<td>-.066 (.56)</td>
<td>-.254 (.03)</td>
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<tr>
<td>Waiting Time</td>
<td>-.169 (.06)</td>
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<td>-.070 (.49)</td>
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<tr>
<td>Deprivation Area</td>
<td>.187 (.06)</td>
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