Research Paper Critique – SAMPLE SOLUTION

Analyzing the Strengths and Weaknesses of a research study

Research Topic: Randomized trial of a brief physiotherapy intervention compared with usual physiotherapy for neck pain patients: outcomes and patients' preference

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Introduction

The objective of this analysis is to study in depth the research results of a study conducted by physiologists to establish whether a cognitive physiotherapy intervention is better than the usual method used by physiotherapists to treat chronic neck pain. The topic is very pertinent today as no method has been established as a fool-proof way to cure neck pain. If the study does show that the brief intervention is as effective as or even better than the usual methods being used today, it could be a significant advance for physiotherapy as neck pain accounts for 15% of all soft tissue problems seen in general practice.

Literature Survey

The authors have put forth an exhaustive survey which helps put their work in the right context. The key findings of the survey are:

- Neck Pain consumes a substantial proportion of healthcare resources
- Very little is known about the effectiveness of the usual treatment provided to patients
- Lack of evidence about the effectiveness of usual treatment in literature
- Interventions which deal with beliefs and worries of patients can help recovery
- Physiologists recommend through one-off sessions a change in lifestyle encouraging patients to take responsibility for their problem apart from the usual exercise they teach them
- In research study where methods are compared or effectiveness is measured, there exists a problem of confounding because patients' own preferences for a particular method affects the outcome. Moreover, unlike in other situations, here the patients cannot be blinded from the method used. A method which does away with this issue is therefore required for un-biased results.

Research Questions

The following research questions are being answered in this study:

1. Compare the effectiveness of a brief cognitive intervention with usual physiotherapy
2. Evaluate the effect of patients' preferences on the treatment outcome

Research Approach Taken: A quantitative approach has been taken by the authors to measure effectiveness of the two treatment methods. Thereafter, statistical analysis has been done on data collected after 3 months and 12 months time to check for how the two methods compare on various parameters.

The comparison is fully randomized, i.e., the allocation of individual patients to the two different methods of treatment in random and has been done telephonically to remove biases. The individual were sourced through referrals by general practitioners and consultants. The referrals were rigorously assessed by the research team to establish whether the referred people were eligible on grounds of age (>18 years), whether they had neck pain for the last two weeks, consent on participation and whether they were willing to take the treatment offered at random. Also, those patients who had serious pathological problems, below elbow pain, those who had received some other treatment recently or neck surgery were removed from the set.

The selection method is good as it removes all biases and confounding from the sample and should provide reliable conclusions.

After the set of patients had been recruited for the study, several measurements were taken as described below. Similar measurements were taken after 3 months and 12 months to evaluate the effectiveness of either method and to conduct a quantitative comparison. The comparison of the two groups clearly shown (Table 2 in the text), that the two groups were homogenous on various parameters. The table is reproduced below:

Table 2 Baseline characteristics of participants included in the study. Values are means (standard deviations) unless indicated otherwise

	Brief intervention (n=139)	Usual physiotherapy (n=129)
Age in years	48.8 (16.56)	47.8 (16.62)
No (%) of patients:		
Women	86 (62)	82 (66)
Expressed preference	64 (46)	62 (48)
Had brief intervention	24 (38)	19 (31)
Had usual physiotherapy	40 (62)	43 (69)
Were indifferent to intervention	75 (54)	67 (52)
Duration of neck pain <6 months	87 (62.6)	88 (68.2)
Northwick Park neck pain score (0-36)	11.33 (4.20)	11.46 (4.32)
SF-36 (0-100):		
Physical functioning	77.15 (17.31)	75.09 (20.40)
Social functioning	73.47 (23.04)	72.19 (22.71)
Role-physical	67.36 (22.87)	67.97 (22.87)
Role-emotional	79.74 (24.12)	76.56 (24.72)
Mental health	70.25 (17.19)	69.71 (18.09)
Energy and fatigue	50.63 (18.81)	48.69 (18.20)
Pain	44.18 (14.68)	45.10 (16.85)
General health perception	66.98 (19.75)	66.10 (17.59)
Tampa kinesophobia score (17-68)	35.15 (6.27)	33.53 (5.55)
Distress (0-10)	4.37 (2.26)	4.09 (2.26)

Higher scores are related to greater severity for all variables, except SF-36, in which lower scores imply worse quality of life.

Measurement Method

Measurements were taken in the form of questionnaires – NPQ (Northwick Park Neck Pain Questionnaire), SF-36 (Generic form used) and the Tampa scale of kinesophobia. The measurements were taken after a period of 3 months and 12 months to measure the short and long term impact of the therapy.

Results

- The authors have shown the result of the treatment on various parameters such as physical functioning, social functioning, physical and emotional role of the treatment, mental health level, energy and fatigue, pain level as well as perceived health level. Further, the Tampa kinesophobia scores were measured to understand the differences in

the two methods. Finally an overall distress level was measured to sum up the effectiveness. These have been shown below:

Outcome	Brief intervention	Usual physiotherapy	Difference (95%CI)	P value (analysis of covariance)
At 3 months' follow up				
Northwick Park neck pain score	−1.481	−2.101	0.620 (−0.444 to 1.684)	0.2518
SF-36:				
Physical functioning	−1.167	1.834	−3.001 (−7.363 to 1.361)	0.1765
Social functioning	2.222	3.005	−0.784 (−6.460 to 4.893)	0.7858
Role-physical	1.932	4.638	−2.706 (−8.646 to 3.234)	0.3703
Role-emotional	−0.179	4.355	−4.533 (−10.020 to 0.954)	0.1049
Mental health	−2.278	2.399	−4.677 (−8.371 to −0.983)	0.0133*
Energy and fatigue	−2.221	2.327	−4.548 (−8.804 to −0.292)	0.0363*
Pain	10.406	11.482	−1.076 (−6.026 to 3.874)	0.6688
General health perception	−4.787	−4.441	−0.346 (−4.076 to 3.385)	0.8552
Tampa kinesophobia score	−1.038	1.196	−2.234 (−3.729 to −0.739)	0.0036*
Distress	−0.693	−0.709	0.016 (−0.520 to 0.552)	0.9545
At 12 months' follow up†				
Northwick Park neck pain score	−0.840	−2.825	1.985 (0.452 to 3.518)	0.0114
SF-36:				
Physical functioning	4.755	7.015	−2.260 (−10.004 to 5.483)	0.5656
Social functioning	−6.466	0.350	−6.817 (−13.445 to 0.141)	0.0548
Role-physical	−0.637	6.064	−6.701 (−12.961 to −0.441)	0.0360*
Role-emotional	−7.268	4.446	−11.715 (−17.571 to −5.858)	0.0001*
Mental health	−9.568	−0.205	−9.362 (−15.053 to −3.671)	0.0014*
Energy and fatigue	−6.735	2.506	−9.241 (−14.663 to −3.819)	0.0009*
Pain	4.994	11.742	−6.749 (−13.18 to −0.380)	0.0379*
General health perception	−9.220	−1.074	−8.146 (−12.347 to −3.946)	0.0002*
Tampa kinesophobia score	−0.309	−0.224	−0.085 (−1.755 to 1.585)	0.9205
Distress	−0.662	−1.047	0.385 (−0.282 to 1.052)	0.2564

*Significant difference at the 5% level (negative Northwick Park questionnaire, Tampa scores, and distress scores indicate improvement; positive SF-36 scores indicate improvement).
†Adjusted for baseline value of the response variable.

- The outcome clearly shows a significant (statistical) preference and win for the usual physiotherapy after 12 months time as is reflected in the Northwick Park neck pain score and the p-value of nearly 0.01. This is however not the case after 3 months. Based on the wide confidence interval it has been concluded that the benefits of the usual physiotherapy is only marginally better than the usual method. Also, on other counts such as general health perception (p~0.0002), Energy and Fatigue (p~0.0009), emotional role (p~0.0001), the usual methodology is significantly better than the brief intervention method.
- Table 4 reproduced below shows the impact of preferences on the outcome. This clearly shows that if people were given the treatment they did not prefer, the NPQ scores

suffered. For the ones who had no preference, i.e. were indifferent, the usual therapy is significantly better than the intervention. This result clearly shows the impact of initial preference on the treatment outcome even if we cannot conclude based on the confidence interval that the effect is significant.

Table 4 Change in Northwick Park neck pain scores at 12 months by patients' baseline preference

	Brief intervention	Usual physiotherapy	
Initial preference	Mean score (95% CI)*	Mean score (95% CI)*	Difference (95% CI)
Indifferent	–1.007 (–2.454 to 0.439) (n=75)	–3.094 (–4.655 to –1.532) (n=67)	2.087 (–0.043 to 4.217)
Brief intervention	–2.811 (–5.431 to –0.190) (n=24)	–2.142 (–4.905 to 0.620) (n=19)	–0.668 (–4.464 to 3.128)
Usual physiotherapy	0.567 (–1.384 to 2.518) (n=40)	–2.750 (–4.650 to –0.849) (n=67)	3.316 (0.589 to 6.044)

*Adjusted for baseline score. Negative scores indicate improvement.

Analysis of the Study - Discussion

Strengths

1. Statistical Robustness: Despite the researchers claimed failure to get a large sample because of slow recruitment and drop outs, the sample size if fairly large (268). This ensures that the reliable statistical conclusions can be drawn.
2. Randomization procedure: An elaborate attempt has been made as part of the research to ensure randomization. This leads to avoidance of any unprecedented bias in the comparison. For example, usage of remote randomization over the telephone as well as usage of blocks of 2-3 patients during allocation ensures that the randomization is as perfect as possible.
3. Taking into account patient preferences: This is different than the usual process wherein patients who prefer their preferences are sent to their preferred procedure whereas only

the patients who are neutral towards the two treatments are randomized. This can lead to confounding. The research under study has taken this into account.

4. Multilevel modeling: This ensured that the impact of clustering (due to several patients being treated by one individual therapist) can be eliminated.

Weaknesses

1. Training: There is a logical flaw in the comparison because of the difference in the competence level of the physiotherapists dealing with the two groups. On one hand there are physiotherapist imparting treatment on which they have an experience and confidence of several years. On the other hand the cognitive treatment is being done by physiotherapists who have been trained for a few days only. Hence, the input going in the treatment is questionable.

   Moreover, all the physiotherapists (irrespective of which group they treated) received the cognitive training. Hence the benefits of the training could inadvertently go to both groups rather than one. This is stated in the research paper itself.

2. Accounting for Psychological factors:
   a. Several psychological factors play a part in therapy – for example patients might feel more comfortable or satisfied if the number of sessions is more – this might show the commitment of the therapist as well which may in turn raise the confidence of the patient.
   b. Also, the individuals' perceived effectiveness of the therapy before the treatment has to be taken into account. This has been done but not in a detailed manner.

c. Psychological impact of undergoing a "new" procedure: Patients might realize that the cognitive method is unusual compared to what they might have seen and this could impact their psychology towards the treatment.

3. Allocation method: The random allocation of patients *after* getting their preferences could potentially lead to dissatisfaction even before the treatment has been delivered. This is proven to have an impact on the outcome. This is also shown in the results of this study (Figure 3 of the paper). This figure is reproduced below:

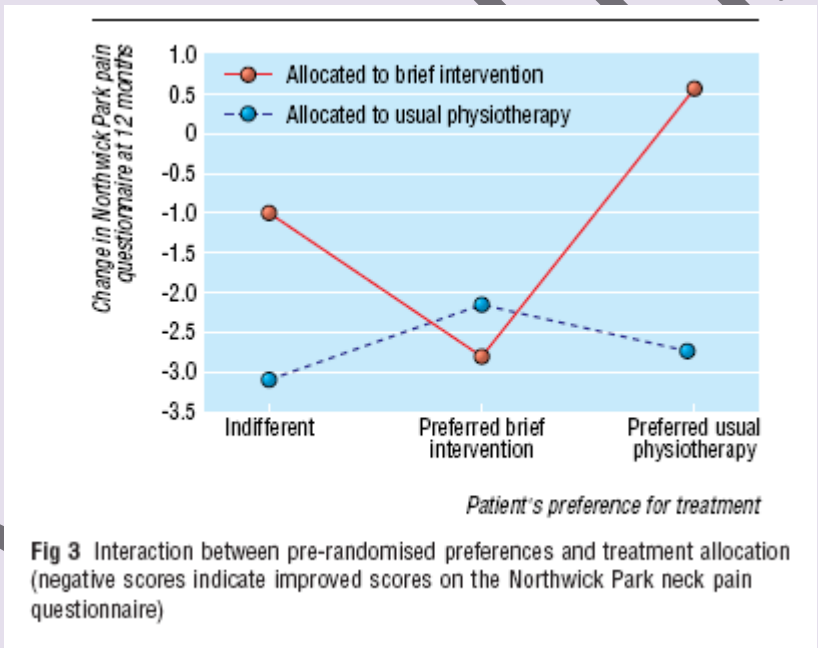

Fig 3 Interaction between pre-randomised preferences and treatment allocation (negative scores indicate improved scores on the Northwick Park neck pain questionnaire)

4. Preference assessment through questionnaire: It has been fairly well documented on how getting preferences through questionnaires can be inaccurate. This is because of the patients' unwillingness to the share their true preference for various factors and phobia.

Conclusion

Despite the limitations of the study pointed out above, there are some clear conclusions that can be derived from the study:

a. Self-management can lead to sustained benefits (evidence available for 12 months) in treatment of chronic neck pain and in some cases can be as good as the usual treatment.
b. The usual method may have marginally higher benefits that self management.
c. A blend of the usual physiotherapy (5 sessions) and one session of cognitive therapy can lead to a better solution which might yield long term benefits for the patient.

The study could have been much more fruitful by removing the trainers' biases and accounting for the individual preferences more robustly than has been in the study. The study also throws up the interesting question of how preferences impact outcome of the treatment. These are directions for potential research and should interest the body of physiotherapy research across the world.

References

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