## Home-based physical activity intervention for breast cancer patients

Pinto BM, Frierson GM, Rabin C, Trunzo JJ, Marcus BH. 2005. Journal of Clinical Oncology . 23(15) 3577-3587.

(Abstract prepared by Cath Smith)

**Purpose:** To determine the effects of a home based moderate intensity exercise programme on physical activity, fitness, mood, physical symptoms and body esteem in women with breast cancer following active cancer treatment.

**Design:** A randomized controlled trial of 86 women to either a monitored physical activity (PA) group or monitored control group, for 12 weeks.

**Intervention:** Following randomization, participants in the PA group received individual instruction on how to exercise at a moderate intensity. They were given home activity logs to record PA participation and encouraged to participate in self selected moderate intensity exercise such as swimming, cycling or walking for which a pedometer was provided. It was suggested that participants initially exercised for 10 minutes per day, two days per week and gradually increased to 30 minutes per day, five days per week by the end of the programme. Each participant received a weekly phone call to address safety issues, barriers to exercise participation and to encourage exercise progression.

Participants in the control group were asked not to change their current level of activity and received a weekly phone call to discuss symptom experience.

**Outcome Measures:** PA was measured both on the Seven-Day Physical Activity Recall and via accelerometry, fitness on the Rockport 1-mile walk test, Stage of Motivational Readiness for Physical Activity Scale, mood on the Profile of Mood States (POMS), fatigue on a linear analogue scale and body esteem on the Body Esteem Scale.

**Results:** Eighty six women were randomized either to a physical activity or a control group; however, there was no power calculation to determine sufficient numbers. Two significant differences between groups at baseline included more control group participants receiving hormone treatment and more control group participants without a spouse or partner. Four women from the physical activity group withdrew from the trial and intention to teat analysis was carried out on all randomized participants. Total weekly energy expenditure and moderate intensity weekly energy expenditure was significantly higher in the physical activity group (p=.001). Time taken to walk one mile was significantly lower in the PA group (p=.001). Participants in the PA group had significantly improved vigour and reduced fatigue (p=.001).

Participants in the PA group were significantly more likely to achieve the American College of Sports Medicine recommendations for physical activity at the end of the trial (p=.001).

**Conclusions:** Physical activity counseling can be delivered effectively via brief weekly phone contact and thus intensive on site interventions are not required to increase physical activity among early stage breast cancer survivors.

### Commentary

This study attempts to evaluate a health promoting exercise intervention which is safe, effective, convenient, low cost and widely applicable amongst breast cancer survivors. Despite perceived safety of this homogenous group there was no indication that preliminary exercise testing was carried out or that baseline physiological measurements of heart rate and blood pressure were taken prior to the intervention. In a population of sedentary, middle aged women rudimentary screening prior to exercise may uncover previously undetected abnormalities and is widely implemented at most community gyms. Participants were instructed on how to exercise at moderate intensity and how to monitor heart rate; however, instructions and methods were not detailed and it is unclear how safely participants were able to self monitor these parameters. Of the four women who withdrew from the trial one cited lack of time, two participants could not be contacted to determine reasons and one developed chest pain during the trial period and was advised to discontinue exercising and see her doctor.

Despite initial reporting of measurement reliability, results are conflicting as accelerometer data does not support significant, self reported increases of PA in the intervention group compared with controls. Significant improvements on the Rockport 1 mile walk test and the fatigue linear analogue scale indicate improved cardiovascular endurance and reduced fatigue for the intervention group. In contrast, psychological improvements, on the POMS, fail to reach significance, which raises an important issue regarding the contribution of social interaction to improved psychological parameters during exercise participation.

Previous studies which have examined the effects of group exercise on both physiological and psychological parameters in people with chronic illness have observed that physiological gains achieved post intervention are maintained at follow up whereas psychological gains such as improved mood are lost (Petajan et al, 1996). Pinto et al (2005) state that follow-up assessments were completed at six and nine months post intervention; however, these results were omitted from the article therefore evaluation of long term effects on all outcomes was not possible. In this study authors concluded that physical activity counselling can be delivered briefly and effectively; however, a key theme identified in a previous study which examined participant experience of a structured multidimensional programme in people with

cancer was the perceived importance of face to face social and professional support (Adamsen et al, 2004).

In summary, the benefits of cheap and convenient health promoting exercise interventions for healthy and non healthy populations must be weighed against possible harm for individuals with low exercise tolerance and potential risk factors. Psycho-social factors such as perceived peer and professional support must also be considered when prescribing therapeutic exercise intervention.

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# Adherence to rehabilitation after anterior cruciate ligament reconstructive surgery

Pizzari, T., Taylor, N.F., McBurney, H. and Feller, J. (2005). Adherence to rehabilitation after anterior cruciate ligament reconstructive surgery: Implications for outcome. Journal of Sport Rehabilitation, 14: 201-214.

(Abstract prepared by Sandra Bassett)

Abstract: This study investigated the relationship between adherence to rehabilitation and treatment outcomes following reconstructive surgery of the anterior cruciate ligament (ACL). Sixty-eight participants were recruited just before or after their surgery. A prospective design was used with rehabilitation adherence measured over the first eight weeks post-operatively and the treatment outcomes assessed at follow-up times of nine and 12 months after surgery. Demographic characteristics, specifically age, occupation, re-injury and sporting level were collected along with the type of graft used and whether there was associated meniscal damage. Adherence was measured by percentage of clinic attendance, and adherence to the clinicbased treatment and home exercise programme. There were six methods of measuring treatment outcomes, which included a clinical examination, two physical activity tests, and three patient selfreports of functional ability.

No significant correlations were found between any of the adherence and treatment outcome scores for the sample as a whole. Splitting the sample on the basis of age showed that in comparison to participants 30 years and older, those under the age of 30 years had significantly better scores at nine months on five treatment outcomes and two outcomes at 12 months. Correlational analysis of the data for the two age groups revealed that in the younger group, there were significant relationships in the expected direction between adherence to home exercises and three of the knee function measures at both measurement times. Also the regression equation for each relationship was significant. In the older age group, there were two significant negative correlations between adherence to home exercises and knee function occurring at nine months. The findings suggest high levels of adherence to home exercises are associated with better functional outcomes in the young group, whereas the older group had poor treatment outcomes if they adhered to their home exercises.

Commentary

This study followed the methodological guidelines for investigating the relationship between rehabilitation adherence and treatment outcomes by using a homogeneous sample in terms of the type of surgery, and a multifaceted approach to the measurement of adherence and treatment outcomes. A homogeneous sample limits variability in responses to the injury and the rehabilitation programme that could confound a study's results. Pizzari et al. selected participants who had undergone an ACL repair, did not have additional knee pathologies and were being treated at one of seven physiotherapy clinics. They also employed a standardised treatment protocol based on that recommended by the four participating surgeons.

The methods of measuring the adherence behaviours were those commonly used in reputable adherence research, and reflected the different behaviours required to undertake the rehabilitation programme, namely clinic attendance (percentage of attendance), and clinic- and home-based adherence. A combination of objective measures and participants' self-report of functional ability was used to measure outcome, which enabled a comprehensive perspective of the participants' recovery. Research that has taken a similar measurement approach has been successful in detecting a significant adherence-outcome relationship (Brewer et al., 2000). Pizzari et al. (2005) could be criticised for using too many participant self-reports, however they did justify their use on the basis of there being no gold standard self-report measures for ACL repairs.

The results of this study highlight two notable issues about the adherence-functional outcome relationship. While Pizzari et al. failed to find any significant relationships when the data was analysed for the entire sample, significant correlations have been identified in other research into adherence to post-operative ACL rehabilitation (Brewer et al., 2000). These conflicting results may be due to the outcome measures being different in the two studies, with those used by Pizzari et al. not being sensitive enough to detect change in this sample. Also the different findings might further reflect the elusive nature of this relationship, as contradictory findings have occurred in studies of exercise programmes for osteoarthritis of the knees [cf. O'Reilly, Muir and Doherty (1999) and van Gool et al. (2005)].

The second notable issue to emerge from the findings relates to the manner in which the adherencefunctional outcomes relationships were interpreted. It cannot be assumed that this relationship is always linear. It may be curvilinear, with high and low levels of adherence being related to poor treatment outcomes, and moderate levels of adherence being associated with optimal outcomes. Such relationships indicate a dose-response effect as has occurred in studies of exercise programmes for osteoarthritis of the knee (Rejeski et al., 1997). While the adherence-functional outcomes relationship was not curvilinear in this study, the conflicting adherence-functional outcome relationships of the two age groups lead Pizzari et al. to interpret this as an example of a dose-response. Support for this interpretation came from the exercise times recorded in the participants' diaries being in excess of the time recommended for optimal muscle fitness and too vigorous for optimal healing of ligamentous tissue in older people. Similar concerns have been expressed by Brewer et al. (2004) about the extensive use of the accelerated post-operative ACL rehabilitation programme.

This study does have two limitations. Using exercise diaries as a measure of home based adherence might not be as ideal as Pizzari et al. stated. Like retrospective self-reports they have been shown to be prone to recall bias and debate surrounds whether they are more of an adherence enhancing strategy instead of measuring it. Finally a greater insight into the adherence-outcome relationship may have been obtained if the measurement of some of the more common determinants of adherence had been included, such as motivation, pain, self-efficacy and social support.

In conclusion the findings of this study highlight the unpredictability of the adherence-treatment outcome relationship, with it not necessarily being a direct correlation between the variables. The suggestion of it being an indication of a doseresponse points to the possibility of it being injury or disease specific and dependent upon the suitability of the treatment protocol.

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## Clinical prediction rule for rapid pain relief of low back pain following manipulation

Childs J.D., Fritz J.M., Flynn T.W., Irrgang J.J., Johnson K,K., Majkowski G.R., Delitto A. A clinical prediction rule to identify patients with low back pain most likely to benefit from spinal manipulation: A validation study. (2004) Annals of Internal Medicine. 141:920-928 (abstract condensed and prepared by Mark Laslett)

**Abstract:** This study was a multicentre randomized controlled clinical trial aimed at validating a clinical prediction rule developed in an earlier study (Flynn et al 2003). Consecutive low back pain patients (n=131) aged 18-60 referred to physical therapy clinics were randomly assigned to receive manipulation plus exercise or exercise alone from a physical therapist over a 4 week period. The patients were examined according to the clinical prediction rule criteria (symptom duration, symptom location, fear avoidance beliefs, and range of passive hip rotation mobility). Disability and pain intensity were measured at baseline, 1, 4 and 26 weeks duration. Those patients satisfying the clinical rule (4 out of 5 criteria are met) had decreased health care utilization at 6 months compared to those patients not satisfying the rule. A patient satisfying the rule and receiving manipulation had odds of a successful outcome of 61 (92% chance) compared to odds of 2.4 for those negative to the rule and receiving manipulation. Those patients satisfying the rule and received exercise only had odds of a successful outcome of 1.0. The number needed to treat for benefit at 4 weeks was 1.9. It was concluded that the clinical prediction rule may be used to select patients most likely to benefit from spinal manipulation.

#### Commentary

In a previous study, some of the current authors presented results of a study aimed at identifying potentially valuable clinical predictors of a good outcome following spinal manipulation (Flynn et al 2003). Following a well defined process of selection using regression modeling, five variables from over 50 demographic, history and physical examination items were found to be useful in identifying patients whose disability (as measured by the Modified Oswestry Disability questionnaire) was reduced by more than 50% in one week. The variables are:

- 1. Symptom duration less than 16 days
- 2. Symptoms do not extend below the knee
- 3. Work subscale score from the Fear Avoidance Beliefs Questionnaire < 19
- 4. Either hip medial rotation (in the prone position) > 35 degrees
- 5. Hypomobility of at least one segment in the lumbar spine (as identified by spring testing to the spinous processes).

The clinical prediction rule (CPR) with the greatest predictive power consisted of 4 of the 5 criteria being met. The positive likelihood ratio among patients meeting at least 4 or the 5 criteria was 24.4 (95%Cl 4.6 to 139.4). The second study was carried out to prospectively validate the CPR in a separate sample. This validation study confirmed the predictive value of the rule where the positive likelihood ratio among patients positive to the rule was 13.2 (95%Cl 3.4 to 52.1) and the negative likelihood ratio among patients satisfying 3 or less criteria was 0.10 (95%Cl 0.03 to 0.41). The change in the Oswestry Disability Questionnaire is illustrated by the graph reproduced (with permission) in Figure 1.

It can be seen that the decline of the Oswestry score for those patients positive to the rule receiving manipulation is significantly better at one week compared to the other three groups. The decline in scores in the other three groups is not significantly different from each other.

The important message from this study and its precursor is that there is a subgroup of low back pain patients for whom manipulation is clearly superior to exercise as a treatment.

It has been known for some years that the classic randomized controlled trial on undifferentiated groups of patients with regional pain complaints (low back pain, shoulder pain etc), almost invariably demonstrates that no one treatment is clearly superior to any other (van Tulder et al 1999). What is significant about these studies is they illustrate how outcomes studies should be conducted in future whereby a development study identifies predictors and clinical prediction rules of an outcome: a diagnostic result or a therapeutic outcome. If predictors are found, a second prospective validation study is conducted to confirm the results.

A secondary result of the first study (Flynn et al 2003) is that the authors were clearly attempting to identify a subgroup of patients with sacroiliac pain or dysfunction that responded to a sacroiliac joint (SIJ) manipulation. Of the fifty variables examined for their predictive power, 18 were provocation, motion and asymmetry SIJ tests. None of these tests had any predictive power. One can conclude that either these SIJ tests have no value in identifying SIJ pain or dysfunction that responds to manipulation or that the manipulation has its effect on structures other that the SIJ, or both.

It can be concluded that: 1. at least one manipulation produces superior outcomes compared to a specific type of exercise program in an identifiable subgroup of low back pain patients 2. no SIJ tests can predict a successful outcome following a SIJ manipulation to acute low back pain patients.

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Figure 1. Figure 3 from Childs et al 2004 (with permission)