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A PILOT STUDY TO DETERMINE THE FEASIBILITY OF A PROSPECTIVE EVALUATION OF THE ARTHRITIS SOCIETY PHYSIOTHERAPY INTERVENTION

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EXECUTIVE SUMMARY

- Program evaluation has been an integral part of The Arthritis Society Consultation and Therapy Service (CTS). The most frequently requested intervention provided by the CTS is physiotherapy (PT) and the most frequently identified disease type referred to the CTS is inflammatory polyarthritis (IP). A randomized controlled trial (RCT) to determine the efficacy of this intervention is running successfully and will be completed in 1995. In order to design this methodologically sound study, a long-term pilot study was performed to establish the operational feasibility of the preliminary RCT design as well as to ensure the suitability of the primary outcome measure and collect data required to calculate sample size.

- People with IP who were referred to 2 CTS offices for a PT intervention during a 2 month period were screened for participation in the study. All consenting clients were assessed by the research assistant at baseline and at 6 weeks. Those clients who met therapy duration criteria of ≥ 4 visits or 3 hours of therapy over the 6 week intervention were reassessed at 3 months, 6 months, and 12 months from baseline.

- Participating clients completed a series of self-administered questionnaires (Stanford Arthritis Self-Efficacy Scales (SES), Visual Analogue Scale for Pain VAS(P)), Arthritis Impact Measurement Scale 2 (AIMS2) and Sickness Impact Profile (SIP), underwent a simple physical examination (joint count, grip strength, assessment of: duration of morning stiffness, sleep disturbance and fibromyalgia tender points), and completed a medication log at each visit. The research assistant had attained reliability in the physical assessment through her training as an independent assessor.

- Eighteen of twenty-five clients referred to the participating CTS offices for a PT intervention were recruited for this study. Sixteen of the 18 consenting clients completed a follow-up assessment. Seventy-five percent (12/16) of these clients had received the intervention of interest (> 4 visits or 3 hours of intervention within 6 weeks).

- Baseline characteristics were similar to those measured in other studies of the CTS client population. The most common client identified problems were similar to those most frequently cited in the results of other studies of this population, the latter of which were used to guide the selection of the chosen outcome measures. A major change to the preliminary RCT design was the determination that a 'stable arthritis medication regimen' requirement was not feasible. None of the feasibility pilot participants maintained a stable arthritis drug regimen throughout the 12 month period of assessment.
Mean change in the SES showed a tendency toward clinically important improvement in self-efficacy similar to that demonstrated by other studies of rehabilitative interventions. These results confirmed the applicability and sensitivity of the SES to clinically important change. This instrument was chosen as the primary outcome measure and the results from the 12 clients who completed this study were used to calculate sample size for the RCT.
A Pilot Study to Determine the Feasibility of a Prospective Evaluation of The Arthritis Society Physiotherapy Intervention

I. Introduction:

The Arthritis Society (TAS), Consultation and Therapy Service (CTS) was established in 1950 to provide home therapy services for clients with rheumatic diseases whose therapeutic needs could best be met in the home setting. The CTS is funded by the Ontario Ministry of Health. In 1991/92, the program provided service to 7,167 people with arthritis and delivered 39,481 visits (mean 5.5 visits/client). CTS currently employs over 57 therapists (Physiotherapists, Occupational Therapists and Social Workers) based in 26 communities, covering an area populated by approximately 95% of Ontario residents. CTS therapists work with family physicians, internists, rheumatologists and other specialists on a referral basis. They also collaborate with Rheumatic Disease Unit treatment teams ensuring continuity of care in the community. Almost 50% of CTS clients have been diagnosed as having IP. The remaining clients have a variety of other arthritic and musculoskeletal disorders. Over 80% of referrals are made for physiotherapy (PT) interventions alone or in combination with occupational therapy or social work.

Clinical objectives of the CTS are: to improve the physical, emotional and social well-being of clients with arthritis; to reinforce and support the work of the health care team by bridging the gap between office visits or hospital care, and the home; to educate the client and immediate family in disease self-management; to provide an individualized physical and/or occupational therapy assessment and management program in the home, school or workplace; to facilitate client alliance with community resources; and, to provide counselling and psychosocial support.

A comprehensive approach to the management of clients with inflammatory polyarthritis (IP) is essential. Often a combination of counselling, PT, occupational therapy, pharmacotherapy and surgery is utilized. The standard PT management includes education about the nature of disease, the need for balancing rest and appropriate activity, and methods to protect joints from trauma and overuse. The use of PT modalities (ie ice and heat) to relieve pain and swelling, and exercise to improve joint mobility, muscle strength and endurance may result in improved function and quality of life.

In 1989, the physiotherapy directors of The Arthritis Society, Ontario Division, performed a chart review from which the ten most frequently identified client problems were selected. This review was followed by a consensus manoeuvre to prescribe appropriate therapeutic interventions for each problem. An internal document entitled, "Inflammatory Arthritis: Management Guidelines" (IAMG), was created and circulated to all therapists in order to standardize PT interventions for CTS clients with IP. A recent chart review of CTS clients with IP found that 96% of client identified problems
fell within the 10 classified in the IAMG. The most frequently recorded interventions were modalities of treatment (exercise, heat, ice, aids etc.) and education.

Published literature describing the evaluation of PT programs is very limited. It has been suggested that the multiplicity of interventions utilized in the management of clients with IP makes it difficult to ascribe improvement in health status to the PT intervention alone. This observation reflects the lack of control groups in most studies published to date. A retrospective chart review identified pain, activities of daily living and lack of disease knowledge as the three problems most often identified by clients who require a CTS physiotherapist intervention. A qualitative evaluation of standard outcome measures identified four questionnaires which were determined to be useful in identifying change in health status due to rehabilitative (versus pharmacologic) interventions for rheumatic diseases. A prospective evaluation of these selected outcome measures identified a trend towards clinically important change in the Stanford Arthritis Self-Efficacy Scale and Visual Analogue Scale for Pain for people with IP with varying disease activity, who participated in a 2 week Multidisciplinary Ambulatory Rheumatology Program (MARP) versus a control group of people with stable disease who received no intervention.

Analysis of visit data abstracted in the retrospective chart review identified that, on average, 60% of all visits took place within the first 6 weeks after the case was opened while the remaining 40% of visits were represented by 'maintenance visits', with follow-up out to one year not uncommon. This proportion is even higher in areas where geographic distance and economic considerations necessitate longer and fewer visits. The mean number of visits to occur within the first 6 weeks of therapy was 3.8; with fewer occurring in areas with geographic restrictions. As over 67% of clients studied achieved resolution or improvement in at least 1 identified problem, a minimum intervention criteria of ≥ 4 visits or 3 hours of intervention within 6 weeks seemed to be an appropriate required intervention duration in order to allow time for change as a result of a CTS PT intervention.

This pilot study was designed to: a) establish the operational feasibility of the preliminary RCT design, and, b) to determine the sensitivity to change of chosen outcome measures in order to calculate sample size for the prospective RCT.

II. Methods:

1. Sample selection

All newly referred clients with confirmed or suspected IP were recruited from the Kingston/Belleville and Toronto/Hamilton CTS offices. All clients scheduled to start a CTS PT intervention during the specified recruitment timeframe, and who met eligibility
criteria, were approached to participate in the pilot study. To maintain blinding, therapists were informed that all clients scheduled to begin therapy within the identified period would be study participants.

2. **Eligibility criteria**

Eligibility criteria screened for men and women with confirmed or suspected IP who were over 18 years of age, did not have a diagnosis of Juvenile Rheumatoid Arthritis, had not been referred for a previous CTS intervention after July 1, 1987, and had the functional ability to participate in the study (i.e. ability to speak and read English; not visually or cognitively impaired).

3. **Assessments**

All consenting clients were assessed by the research assistant at baseline and at 6 weeks. Clients who received the intervention of interest (≥ 4 visits or a time equivalent of 3 hours of therapy within 6 weeks) participated in follow-up assessments which occurred at 3 months, 6 months, and 12 months after baseline.

4. **Outcome measures**

Participating clients completed a series of self-administered questionnaires which included the: Stanford Arthritis Self-Efficacy Scale, Visual Analogue Scale for Pain, Arthritis Impact Measurement Scales, and the Sickness Impact Profile. Subjects also underwent a simple physical examination of joint count, grip strength, and assessment of duration of: morning stiffness, sleep disturbance and fibromyalgia tender points. The research assistant completed a medication log and confirmed demographic variables each visit. The research assistant had attained reliability in the physical assessment through her training as an independent assessor. Standard charting procedures require the CTS physiotherapists to record total number of visits as well as duration of visits on a prospective basis, therefore this data was collected for each participating client and recorded on the client’s chart. Blinded copies of participating client’s charts were sent from the CTS office to the study team once therapy was concluded.

5. **Analysis**

Data was managed and analyzed using SPSS PC+ Version 4.0 data entry and statistical package. Over 10% of all data entries were verified and the error rate was deemed acceptable (< 1%). Due to the nature of the analysis, missing data was minimal and, where necessary, considered in the interpretation of results.
Mean scores were compared by the Student's t-test or analysis of variance, with \( p \leq .05 \) considered statistically significant. Correlations were assessed with Pearson's correlation coefficients.

### III. Results

Recruitment was conducted from 22 June 1992 to 17 August 1992. Eighteen of twenty-five clients referred to the participating CTS offices for a PT intervention were recruited for this study. Sixteen of the 18 consenting clients completed a follow-up assessment. Seventy-five percent (12/16) of these clients had received the intervention of interest (> 4 visits or 3 hours of intervention within 6 weeks) and were included in efficacy analysis.

Eighty three percent of the study participants were women; mean age was 58.9 years and mean disease duration was 6.5 years at baseline. These demographics are very similar to previous CTS client profiles.\(^{20,33}\)

#### Table 1: Baseline characteristics

<table>
<thead>
<tr>
<th></th>
<th>( n = 12 )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td>% female</td>
</tr>
<tr>
<td></td>
<td>mean years (SD)</td>
</tr>
<tr>
<td>Age</td>
<td>% married/common-law</td>
</tr>
<tr>
<td>Marital Status</td>
<td>% ≥ grade 11</td>
</tr>
<tr>
<td>Education</td>
<td>% ≥ $20,000</td>
</tr>
<tr>
<td>Household Income</td>
<td>% currently employed</td>
</tr>
<tr>
<td>Employment Status</td>
<td>mean years (SD)</td>
</tr>
<tr>
<td>Disease Duration</td>
<td>% taking daily meds</td>
</tr>
<tr>
<td>Arthritis Medication</td>
<td>% taking daily meds</td>
</tr>
<tr>
<td>Other Medications</td>
<td></td>
</tr>
</tbody>
</table>

Mean change in the SES showed a tendency toward clinically important improvement in self-efficacy which was similar to other rehabilitative studies for arthritis (Table 2). The relevance of the SES in this population has been discussed elsewhere.\(^{21}\)

Improvement in VAS(P) supports the change in the SES, and this improvement was further supported by change in clinical variables and relevant AIMS2 domain scores.
Table 2: Mean Change Scores: Prospective Evaluation of Selected Health Status Measures versus Various Arthritis Self-Management Studies

<table>
<thead>
<tr>
<th>EXPERIMENTAL GROUP</th>
<th>V A S</th>
<th>STANFORD ARTHRITIS SELF-EFFICACY SCALE</th>
<th>Clinically Important Change using Pain Control &amp; Other Symptoms combined</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>PAIN YESTERDAY</td>
<td>PAIN CONTROL</td>
<td>OTHER SYMPTOMS</td>
</tr>
<tr>
<td></td>
<td>mean (SD)</td>
<td>% Improved</td>
<td>mean (SD)</td>
</tr>
<tr>
<td>≥ 4 visits/3 hours within 6 weeks</td>
<td>12</td>
<td>-1.5 (2.7)</td>
<td>15</td>
</tr>
<tr>
<td>Change at 3 months (from baseline)</td>
<td>12</td>
<td>-1.5 (2.4)</td>
<td>15</td>
</tr>
<tr>
<td>Change at 6 months (from baseline)</td>
<td>12</td>
<td>-0.4 (3.1)</td>
<td>5</td>
</tr>
<tr>
<td>Change at 12 months (from baseline)</td>
<td>11</td>
<td>-2.2 (3.5)</td>
<td>22</td>
</tr>
<tr>
<td>Multidisciplinary Ambulatory Rheumatology Program 10 days</td>
<td>5</td>
<td>-1.4 (3.4)</td>
<td>14</td>
</tr>
<tr>
<td>Arthritis Self Management Course 4 months (Lorig et al. 1989)</td>
<td>95</td>
<td>-1.3 (2.4)</td>
<td>13</td>
</tr>
<tr>
<td>Stanford (presented in BC 1992)</td>
<td>97</td>
<td>1</td>
<td>14</td>
</tr>
<tr>
<td>BC (presented in BC 1992)</td>
<td>146</td>
<td>9</td>
<td>7</td>
</tr>
<tr>
<td>CONTROL GROUP</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No Intervention 4 weeks</td>
<td>5</td>
<td>-0.4 (1.1)</td>
<td>4</td>
</tr>
<tr>
<td>Arthritis Self Management Course 4 months (Lorig et al. 1989)</td>
<td>49</td>
<td>-0.3 (1.8)</td>
<td>3</td>
</tr>
</tbody>
</table>
Analysis of the long-term outcome measure, the SIP, identified scores which had changed minimally over the 12 months of follow-up. The AIMS2 demonstrated levels of change which correlated to change in physical status as indicated by the SES, VAS (P), and chart variables. The highest proportion of change from baseline occurred immediately after the intervention and this improvement was on average maintained to month 12.

During the 6 week intervention period, 2 of 12 clients underwent changes in DMARD and prednisone therapy; between 6 weeks and 3 months, 4 clients underwent drug dose changes. During the 3 to 6 month follow-up interval 7 clients experienced DMARD and prednisone modifications and alterations in therapy during the 6 to 12 month follow-up interval occurred in 6 clients. Through the study, changes in NSAID doses also occurred frequently. In conclusion, there was no individual client who had stable arthritis drug therapy throughout the 12 month period of assessment.

A review of the 12 client charts upon completion of therapy identified 56 problems addressed by the therapists throughout the course of the intervention. Over 68% of these problems were resolved or improved by discharge. Of the resolved or improved problems, 63% were pain related, 13% addressed disease knowledge and management, and 11% addressed activities of daily living (Table 3). These results are similar to the conclusions of a retrospective chart review of 57 CTS clients\textsuperscript{20}, indicating the relative homogeneity of subsamples of this population. In total, eleven of the 12 participating clients had resolution or improvement of at least one problem at discharge.

<table>
<thead>
<tr>
<th>Problem</th>
<th>f</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>24</td>
<td>63</td>
</tr>
<tr>
<td>Limited Knowledge of Disease Management</td>
<td>5</td>
<td>13</td>
</tr>
<tr>
<td>Limited Activities of Daily Living</td>
<td>4</td>
<td>11</td>
</tr>
<tr>
<td>Limited Joint Range of Motion</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>Decreased Muscle Strength</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Joint Swelling and Effusion</td>
<td>2</td>
<td>5</td>
</tr>
</tbody>
</table>

Table 3: Problems Resolved or Improved as Charted by the Therapists
IV. Conclusions

Our experiences with the Feasibility Pilot compelled us to reconsider several a priori hypotheses which were used in the preliminary design of the RCT, the most important being an inclusion criteria of 'stable arthritis medications' only. We learned that to include this criteria in study methodology would a) impact significantly on recruitment, and, b) result in study conclusions which were not reproducible in the real CTS client population since many clients are referred for CTS services at disease onset and during disease flares.

The required frequency and duration of intervention, > 4 visits or 3 hours of therapy in 6 weeks, appeared appropriate as 75% of the clients who participated in a post-therapy assessment had received enough intervention for change to be identified, and for 8 of these 12 clients, therapy was finished by 6 weeks or shortly thereafter.

A retrospective chart review of the 12 clients who participated in this study indicated that the most frequently identified problems to be resolved by the end of therapy were those identified in the retrospective chart review which facilitated the selection of the outcome measures used. This pilot study demonstrated the appropriateness of the chosen outcome measures in identifying the physical, psychological and social domains in which an intervention was most likely to be required, and in evaluating change as a result of an intervention.

The results of the Feasibility Pilot also confirmed the applicability and sensitivity of the SES to clinically important change. This measure has shown promise as a primary outcome measure and the results from the 12 clients who completed this were used to calculate sample size for the RCT. As improvement in SES scores was maintained to 6 and 12 months, at least one comprehensive longterm follow-up assessment was also added to the RCT design.

This feasibility study was not only instrumental in facilitating the final design of the prospective RCT to evaluate the efficacy of the CTS PT intervention, but also demonstrated the necessity for pilot work to determine operational feasibility and appropriateness of selected outcome measures when designing any major research project.
REFERENCES