Effectiveness of a Structured Physical Rehabilitation Program for Chinese Population with Depressive Disorders

Lau MYP\textsuperscript{1}, Ng MKR\textsuperscript{2}, Tsang WKA\textsuperscript{2}, Yu HSZ\textsuperscript{3}, Ng KM\textsuperscript{2}, Chan CT\textsuperscript{2}, Chau MWR\textsuperscript{1}, Lam MYMay\textsuperscript{1}, Tang LWF\textsuperscript{1}, Lo YKP\textsuperscript{1}, Lau WL P\textsuperscript{1}, Chan SHF\textsuperscript{1}, Lau WYM\textsuperscript{4}

Physiotherapy Department, Kowloon Hospital\textsuperscript{1}; Department of Psychiatry, Kowloon Hospital\textsuperscript{2}; Department of Psychiatry, Kwai Chung Hospital\textsuperscript{3}; Physiotherapy Department, Kwai Chung Hospital\textsuperscript{4}

HA Convention

15 May 2013
Depression

- closely related to ↓ physical fitness, exercise habit & social activity level (Hoffman et al., 2011)
- ↑ complaint of pain frequency & severity (Katona et al., 2005)
- **Exercise** - sig ↓ the negative symptoms (Hoffman et al., 2011; Mead et al., 2009; Rethorst, Wipfli & Landers, 2009)
- **Socio-cultural influence** on manifestations of clinical signs & symptoms of mental health problems between Chinese & Western societies (Pearson & Liu, 2002; Pearson et al., 2002; Tam and Wong, 2007)
  - ↑ likelihood of somatization (Parker, Chan et al., 2005; Xiang et al., 2008)
  - avoid seeking help for psychiatric problems (Parker, Chan, et al., 2005)
- Paucity of published studies on the benefits of exercises in the management depressive disorders among Chinese population
Multi-centers Collaborative RCT - Physical Rehabilitation Program for Patients with Depressive Disorders

Aim of the study

- To investigate the effectiveness of a holistic, structured Physical Rehabilitation Program on improving the physical fitness and negative psychological symptoms for Chinese patients with mild to severe depressive disorders

Research Design

- Single-blind randomized controlled trial (RCT)
RCT Registration

Protocol Registration Receipt
02/23/2012

Effectiveness of a Structured Physical Rehabilitation Program for Chinese Patients With Depressive Disorders

This study is currently recruiting participants.
Verified by Dr. Lau Mo Yee Polly, Kowloon Hospital, Hong Kong, February 2012

<table>
<thead>
<tr>
<th>Sponsor:</th>
<th>Kowloon Hospital, Hong Kong</th>
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<tr>
<td>Collaborators:</td>
<td>Kwai Chung Hospital, Hong Kong</td>
</tr>
<tr>
<td>Information provided by (Responsible Party):</td>
<td>Dr. Lau Mo Yee Polly, Kowloon Hospital, Hong Kong</td>
</tr>
<tr>
<td>ClinicalTrials.gov Identifier:</td>
<td>NCT01536756</td>
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US National Institute of Health (NIH), developed by the National Library of Medicine
Methodology - Subjects

**Inclusion Criteria**
1. ages 18 to 64 adults
2. diagnosed depressive disorders of mild to severe severity (Diagnostic code: F32.0 to F33.9 of ICD 10)
3. referred from the Department of Psychiatry of Kowloon Hospital or Kwai Chung Hospital
4. able to read, write and understand Chinese
5. mentally capable of making written consent for participation of study

**Exclusion Criteria**
1. unstable medical and/or psychological states such as suicidal risk and aggressive impulses
2. severe cognitive, language, or hearing deficits
3. any orthopaedic problems or other diseases which limit physical fitness assessment
Study Design

Patients with Diagnosis of Depressive Disorder

Intake Baseline Assessment (T1)

Block Randomization by StatsDirect (ver 2.7.8) with block size of 6

Intervention (n=42)
12-week Structured Physical Rehabilitation Program

Control (n=42)
Waiting List Control

12 week Re-assessment (T2)

Intervention (n=42)
12 month long term follow up (T3)

12 week Re-assessment (T2)

Sample Size Calculation

- Power Analysis & Sample Size Program (PASS 2011, NCSS Statistical Software) with a priori power analysis
- \(\alpha = 0.05\) & power = 0.8 to detect a group difference of medium effect size in reduction of mental health symptoms score and increment in physical health parameters (Rampello et al., 2007; Mead et al., 2009; Rethorst, Wipfli and Landers, 2009)
- 20% of attrition rate suggested by previous articles (Blumenthal et al., 1999; Herman et al., 2002; Blumenthal et al., 2007)
Instrumentation - Physical outcome measures

1. **Body composition** - body mass index – BMI (kg/m$^2$), % body fat by bioelectrical impedance analysis with Body Composition Analyzer (InBody R20®, Biospace Co., Ltd., Seoul, Korea.) (Eckerson et al., 1997; Sun et al., 2005)

2. **Flexibility** - sit & reach flexibility (cm) (ACSM, 2010; Jackson & Baker, 1986)

3. **Muscular endurance** - 1-minute sit-up count (Brower, 2009; Durmus, Durmaz and Canturk, 2010)
4. **Muscle strength**
   - hand grip strength by **JAMAR dynamometer** (kg), Digital Hand Dynamometer (Patterson Medical Supply, Inc., Bolingbrook, USA) (Castro-Pinero et al., 2009; Rantanen et al., 1999, 2003; Tsang, 2005)
   - isometric quadriceps strength by **Hand Held Dynamometer** (HHD) (kg), Nicholas Manual Muscle Tester (Lafayette Instrument Co., Indiana, USA; Tsepis, Vagenas) (Giakas & Georgoulis, 2004; Hairi et al., 2010; Hebert et al., 2010; Singer et al., 2011)

5. **Cardiovascular endurance** - maximal oxygen consumption ($\text{VO}_2 \text{ max-ml/kg/min; MET}$) by using **Submaximal Bike Test with FitMate** PRO (Cosmed, Rome, Italy) (ACSM, 2010; Nieman et al., 2006, 2007)

   Self-rated pain assessment questionnaire for the assessment of pain-related functioning impairment in 7 daily activities, including general activity, walking, work, mood, enjoyment of life, relations with others and sleep (Range – 0-10; ↑ score, ↑ pain inferences)
1. **Depression, Anxiety, Stress Scale (DASS-21) - Chinese version (情緒自評量表)**

(Brown, Chorpita, Korotitsch and Barlow, 1997; Ng et al., 2007; Taouk, Lovibond and Laube, 2001)

A set of 3 self-report scales designed to measure the negative emotional states of depression, anxiety and stress & recommended cut-off scores for conventional severity labels.

Each of the 3 DASS-21 sub-scales contains 7 items (range of each subscore = 0-21; ↑ score, ↑ severity)

Rated on 4-point severity or frequency scales to rate the extent which the individual have experienced each state over the past week.

Validated & supported the ability to reflect clinical status & changes across treatment in a clinical population (Ng et al., 2007)

Good internal consistency of the 3 scales of DASS-21, with Cronbach’s alpha = 0.96, 0.89 and 0.93 for depression, anxiety & stress.

![Table 1](image)
Intervention-Physical Rehabilitation Program

- **Intensity**
  - 60-min training session; 3 times per week for 12-week

- **Core element**
  - aerobic exercise (ACSM, 2010; NICE, 2010)
  - resistance training (ACSM, 2010; NICE, 2010)
  - body awareness training (Olsson, Armelius & Aremelius, 2001)
  - exercise habit coaching

- **Auxiliary intervention for pain**
  - Interferential therapy & hot pad (Ernst et al, 2011; Kim et al., 2009; Mead et al., 2009; Rethorst et al, 2009; Ruth & Vlack, 2010; YWatson, 2008; Yang et al, 2010; Zhou et al., 2010)
Stretching & mindful breathing for stress management (Zautra, Fasman, Davis & Craig, 2010).
40-min Circuit Training

Aerobic exercises for physical work up

- 3 sets of 10 repetitions
- moderate level
- 50-70% of HR max

Strengthening exercises of major muscles groups
- **Intraclass correlation coefficient** (ICC$_{3,1}$) for the intra-rater test-retest reliability test-retest reliability of the physical outcome measures

<table>
<thead>
<tr>
<th>Outcome measures</th>
<th>ICC value</th>
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<tbody>
<tr>
<td>BMI</td>
<td>1.00</td>
</tr>
<tr>
<td>% body fat</td>
<td>1.00</td>
</tr>
<tr>
<td>Sit and reach flexibility</td>
<td>0.97</td>
</tr>
<tr>
<td>1 minute sit-up count</td>
<td>0.99</td>
</tr>
<tr>
<td>Hand grip strength</td>
<td>0.99</td>
</tr>
<tr>
<td>Quadriceps strength</td>
<td>0.97</td>
</tr>
<tr>
<td>METS</td>
<td>0.92</td>
</tr>
<tr>
<td>VO$_2$ max</td>
<td>0.93</td>
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*Good Reliability*
Statistical Analysis

- Statistical Package for Social Sciences (SPSS) software, ver 19.0

- Descriptive statistics of means and range was used for the analysis of the demographic data

- Wilcoxon signed ranks test for within-group difference

- Mann-Whitney U test for between groups comparison

- Level of significance set at $p < 0.05$

- Intention-to-treat analysis
### Result – Demographic data

<table>
<thead>
<tr>
<th></th>
<th>Intervention Group (n = 28)</th>
<th>Waiting Control (n = 25)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yr), Mean (SD)</td>
<td>46.8 (12.1)</td>
<td>46.9 (9.4)</td>
</tr>
<tr>
<td>Gender (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>6 (21.4)</td>
<td>5 (20.0)</td>
</tr>
<tr>
<td>Female</td>
<td>22 (78.6)</td>
<td>20 (80.0)</td>
</tr>
<tr>
<td>Height m</td>
<td>1.58 (0.1)</td>
<td>1.59 (0.1)</td>
</tr>
<tr>
<td>Weight Kg</td>
<td>61.4 (10.6)</td>
<td>64.5 (10.3)</td>
</tr>
<tr>
<td>Body Mass Index</td>
<td>24.6 (3.7)</td>
<td>25.4 (4.1)</td>
</tr>
</tbody>
</table>

Comparable baseline characteristics with $p>0.05$
Result – Physical Outcomes (1)

BMI

% Body Fat

1.2% ↓

9.3% ↓
Result – Physical Outcomes (2)

Sit-up Count

Sit-up Count

Sit & Reach

Sit & Reach

125% ↑

346% ↑
Result – Physical Outcomes (3)

Hand Grip Strength
18.3% ↑

Quadriceps Strength
19.5% ↑
Result – Physical Outcomes (4)

Exercise Endurance
Submaximal Bike Test (VO2 max)
27.4% ↑

Pain Interference
27.3% ↓
Result – Mental Outcomes (1)

**DASS**

**Depression Domain**
- Intervention Group vs. Control
  - T1
  - T2

**Anxiety Domain**
- Intervention Group vs. Control
  - T1
  - T2

**Stress Domain**
- Intervention Group vs. Control
  - T1
  - T2

- Depression Domain: 48.6%↓
- Anxiety Domain: 36.1%↓
- Stress Domain: 28.2%↓
Summary of Results

- The physical profile of all patients below Hong Kong norm

- **Significant improvement** in all physical & mental outcome measures for intervention group after 12-week physical rehabilitation program

- When compared with control group,
  - Significant improvement in **physical outcome** except BMI & pain interference not reaching statistical significant level
  - Significant improvement in **mental outcome** including all 3 domains (depression, anxiety & stress)
  - Significant difference in the % of changes of all physical & mental outcome measures
Discussions

Significant improvement in physical outcome

- Benefits of exercises in improving physical fitness well documented in medical literatures (ACSM, 2009; 2010; Keith, 2004; Thase, 2007; Plante et al, 2007) e.g. \[\uparrow\] strength & cardiovascular endurance, \[\downarrow\] body fat, preserving fat-free mass
Significant improvement in mental outcomes

- findings accord with that of overseas studies – ↓ mild to moderate depression alone or in combination with other treatments (Donaghy, M, & Durward, B. 2000; Larun et al 2006)
- ↑ plasma beta-endorphin inducing a temporary mood elevation & relaxation effects (Craft LL et al, 2004; Sylvia et al., 2009)
- as an outlet for individuals to discharge negative emotions in a healthy, safe & acceptable manner;
- altering negative thinking style (Ekeland et al, 2004; Mike Carrera, 2002)
- Benefits also detected in Chinese patients
Discussions

Avoid seeking help for psychiatric problems in Chinese

- Augmented by positive encouragement from healthcare team
- Positive influences / motivation from peers
- Provides peer ventilation, mutual support that foster commitment, and the common goal of achievement, \( \uparrow \) compliance (\( \downarrow \) dropout) (Yalom & Leszes, 2005)
- \( \downarrow \) labeling effect
Clinical Implications

- Cultural validation of the effects of structured physical rehabilitation program in Hong Kong Chinese patients with depressive disorder
- Information on physical profile, pain prevalence & mental profile will provide valuable data for better service planning
- New service package focusing on engaging and empowering patients with depressive disorders to be co-producer of the treatment outcomes
  - from hospital based transition of care to future community-based sustainable home care
  - decreased labeling effect of patients with mental health problems
Limitation

- This study was designed specifically for Chinese populations and the findings may not be applicable to non-Chinese patients with depressive mood disorders.

- Patients with suicidal risk are not included in this study.
Conclusions

- RCT in progress

- the preliminary results suggested that a comprehensive physical rehabilitation program could be an **effective** intervention to improve physical fitness & negative psychological symptoms for **Chinese** patients with depressive disorder

- All subjects were highly satisfied with the program
Acknowledgements

Special thanks to all of the participants of this study

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Thank You!

Psychiatric Therapy
References


References

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