Can Exercise Enhance Smoking Cessation Outcomes?
A Pragmatic Randomized Controlled Trial
(Fit2Quit Study)

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Key Facts in New Zealand

• There are currently 650,000 smokers in NZ
  – 21% of adults are current smokers
  – 45% of Māori smoke, with 49% in women and 40% in men
  – 30% of Pacific peoples, 20% of European/others, 11% of Asian smoke

• 5,000 people die from smoking-related illness each year
  – Tobacco is the leading cause of preventable death
  – Smokefree Aotearoa NZ 2025 is an official Government goal

• 80% of smokers would not smoke if they had their life over again
  – Common reasons for quitting: own health (78%), cost (41%), sick of smoking (37%) and someone else’s health (26%)
    • A pack-a-day smoking habit costs around $5000 each year

• Exercise has been proposed to aid smoking cessation
  – Needs for larger trials with sufficiently intense interventions
• A charitable trust established in 1999 as the national cessation agency funded by the Ministry of Health

The Quitline - 0800 778 778

Call the Quitline for free advice and non-judgmental support to quit smoking.

An advisor will talk you through the three parts of the smoking addiction - chemical, emotional and habitual. Through Quitline you can order subsidized nicotine patches, gum or lozenges - $3 for an 8 week supply. We'll also send you a Quit Pack with resources to support you.

• Quitline supports around 12,000 people to successfully quit each year
  – 9% of the smoking population accesses Quitline each year
  – 21% of Quitline clients are Māori, 5% Pacific peoples
  – 20.9% of Quitline clients are quit at six months
    • 5 times the success rate for those who quit alone (~4%)
Green Prescription Programme (GPx)

- A clinician based initiative in general practice that provides counseling on physical activity
- Proved to be effective in increasing physical activity and improving quality of life over 12 months (Elley et al, BMJ 2003, 326:793-796)

The “green prescription” intervention
- Primary care clinicians are offered four hours of training in how to use motivational interviewing techniques to give advice on physical activity and the green prescription
- Patients who have been identified as “less active” through screening at the reception desk and who agree to participate receive a prompt card, stating their stage of change, from the researcher, to give to the general practitioner during consultation
- In the consultation, the primary care professional discusses increasing physical activity and decides on appropriate goals with the patient. These goals, usually home based physical activity or walking, are written on a standard green prescription and given to the patient
- A copy of the green prescription is faxed to the local sports foundation with the patient’s consent. Relevant details such as age, weight, and particular health conditions are often included
- Exercise specialists from the sports foundation make at least three telephone calls (lasting 10-20 minutes) to the patients over the next three months to encourage and support them. Motivational interviewing techniques are used. Specific advice about exercise or community groups is provided if appropriate
- Quarterly newsletters from the sports foundations about physical activity initiatives in the community and motivational material are sent to participants. Other mailed materials, such as specific exercise programmes, are sent to interested participants
- The staff of the general practice is encouraged to provide feedback to the participant on subsequent visits to the practice
The Fit2Quit Trial

• Design
  – A prospective, multi-centre, parallel, two-arm, randomised controlled trial

• Objectives
  – To examine the effect of a home and telephone-based exercise programme (GPx) over six months, in addition to usual smoking cessation support from Quitline, on
    ▪ Smoking abstinence
    ▪ Mood and physical symptoms
    ▪ Physical activity levels
    ▪ Body size, physical fitness, and psychological factors
      (face to face interviews only)
Trial Flow Chart

- Recruitment & baseline data collection
  - Randomisation

Quit day (Day 0)

- Intervention
  - Weekly phone support
  - Smoking cessation treatment
  - Phone support (avg 3 calls) + NRT

4 weeks

- Fortnightly phone support
- Exercise

8 weeks

- Monthly phone support
- Smoking cessation treatment
- Phone support (avg 3 calls) + NRT

6 months

- Outcome data collected
A higher proportion of withdrawals was observed in the intervention group, for potentially two reasons:

- Frequent intervention calls during 6 months;
- Not having quit smoking;
## Baseline Characteristics

<table>
<thead>
<tr>
<th>Baseline Variables</th>
<th>Intervention</th>
<th>Control</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type of Interview</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Face to Face</td>
<td>109 (24.2%)</td>
<td>110 (24.2%)</td>
<td>219 (24.2%)</td>
</tr>
<tr>
<td>Telephone</td>
<td>342 (75.8%)</td>
<td>345 (75.8%)</td>
<td>687 (75.8%)</td>
</tr>
<tr>
<td><strong>Age (in years)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>37.3 ± 12.16</td>
<td>37.6 ± 12.25</td>
<td>37.5 ± 12.20</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Males</td>
<td>207 (45.9%)</td>
<td>208 (45.7%)</td>
<td>415 (45.8%)</td>
</tr>
<tr>
<td>Females</td>
<td>244 (54.1%)</td>
<td>247 (54.3%)</td>
<td>491 (54.2%)</td>
</tr>
<tr>
<td><strong>Ethnicity</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maori</td>
<td>138 (30.6%)</td>
<td>142 (31.2%)</td>
<td>280 (30.9%)</td>
</tr>
<tr>
<td>Pacific</td>
<td>55 (12.2%)</td>
<td>47 (10.3%)</td>
<td>102 (11.3%)</td>
</tr>
<tr>
<td>Asian</td>
<td>11 (2.4%)</td>
<td>13 (2.9%)</td>
<td>24 (2.6%)</td>
</tr>
<tr>
<td>NZEO</td>
<td>247 (54.8%)</td>
<td>253 (55.6%)</td>
<td>500 (55.2%)</td>
</tr>
<tr>
<td><strong>Strength of Urge to Smoke (SUTS)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No urge (0)</td>
<td>12 (2.7%)</td>
<td>10 (2.2%)</td>
<td>22 (2.4%)</td>
</tr>
<tr>
<td>Slight (1)</td>
<td>53 (11.8%)</td>
<td>66 (14.5%)</td>
<td>119 (13.1%)</td>
</tr>
<tr>
<td>Moderate (2)</td>
<td>138 (30.6%)</td>
<td>148 (32.5%)</td>
<td>286 (31.6%)</td>
</tr>
<tr>
<td>Strong (3)</td>
<td>139 (30.8%)</td>
<td>146 (32.1%)</td>
<td>285 (31.5%)</td>
</tr>
<tr>
<td>Very strong (4)</td>
<td>71 (15.7%)</td>
<td>49 (10.8%)</td>
<td>120 (13.2%)</td>
</tr>
<tr>
<td>Extremely strong (5)</td>
<td>36 (8.0%)</td>
<td>35 (7.7%)</td>
<td>71 (7.8%)</td>
</tr>
<tr>
<td>Missing</td>
<td>2 (0.4%)</td>
<td>1 (0.2%)</td>
<td>3 (0.3%)</td>
</tr>
</tbody>
</table>

* Confounding factors considered in regression analysis
Smoking History and Dependency at Baseline

- The average age started smoking was 15.5 years old, and smoked continuously for 20 years with 20 cigarettes and/or RYO each day
- 79% of participants made previous attempts to stop smoking
  - 43% made at least one attempt in last 12 months and lasted for an average of 35 days
  - Most used nothing to help stop smoking that time
- 83% of participants smoked >10 cigarettes per day
  - 44% smoked 11-20 cigarettes per day
  - 28% smoked 21-30 cigarettes per day
- One third had the first cigarette within 5 minutes of waking
- Over 60% of participants felt that the cigarette they would most hate to give up was the first one in the morning
- 55% didn’t use NRT at baseline
• Two smoking outcomes are of particular interest:
  – Seven days point prevalence (PP)
    ▪ whether had a single puff of a cigarette or roll-your-own in the last 7 days
  – Continuous abstinence
    ▪ whether had smoked more than 5 cigarettes or roll-your-own since the nominated quit date

• Self-reported quitters were further validated with a measure of salivary cotinine using NicAlert™ test strips
  – Quit status was confirmed with a salivary cotinine reading of <15ng/mL, or the concurrent use of NRT when the reading was 15ng/mL or more

• ITT analysis: missing as smokers (i.e. treatment failure)
7 Days PP (ITT population)

24 Weeks Assessment:

Case 1:

ITT analysis (N=906)
Self-reported point prevalence confirmed by salivary cotinine reading of less than 15ng/mL or use of NRT when the cotinine reading is ≥15ng/mL

Case 2:

ITT analysis (N=906)
Self-reported point prevalence only

Primary Outcome

(Sensitivity Analysis)
7 Days PP (Complete Cases)

24 Weeks Assessment:

Case 3:
Complete-Case Analysis (N=596) Self-reported point prevalence confirmed by salivary cotinine reading of less than 15ng/mL, or use of NRT when the cotinine reading is ≥15ng/mL.

Case 4:
Complete-Case Analysis (N=683) Self-reported point prevalence only.

(Sensitivity Analysis)
## Treatment Evaluations at 24 Weeks

<table>
<thead>
<tr>
<th></th>
<th>Quit Rate</th>
<th>*Relative Risk</th>
<th>*Odds Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Intervention</td>
<td>Control</td>
<td>Estimate</td>
</tr>
<tr>
<td><strong>ITT population</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cotinine verified</td>
<td>9% (42/455)</td>
<td>11% (48/451)</td>
<td>1.02</td>
</tr>
<tr>
<td>Self reported</td>
<td>23% (105/455)</td>
<td>22% (98/451)</td>
<td>0.98</td>
</tr>
<tr>
<td><strong>Complete cases</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cotinine verified</td>
<td>15% (42/277)</td>
<td>15% (48/319)</td>
<td>1.00</td>
</tr>
<tr>
<td>Self reported</td>
<td>32% (105/328)</td>
<td>28% (98/355)</td>
<td>0.94</td>
</tr>
</tbody>
</table>

* Probability of smoking

### Continuous Abstinence

<table>
<thead>
<tr>
<th></th>
<th>Quit Rate</th>
<th>*Relative Risk</th>
<th>*Odds Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Intervention</td>
<td>Control</td>
<td>Estimate</td>
</tr>
<tr>
<td><strong>ITT population</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cotinine verified</td>
<td>7% (32/455)</td>
<td>9% (41/451)</td>
<td>1.02</td>
</tr>
<tr>
<td>Self reported</td>
<td>17% (78/455)</td>
<td>18% (80/451)</td>
<td>1.01</td>
</tr>
<tr>
<td><strong>Complete cases</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cotinine verified</td>
<td>11% (32/288)</td>
<td>13% (41/324)</td>
<td>1.02</td>
</tr>
<tr>
<td>Self reported</td>
<td>24% (78/326)</td>
<td>23% (80/354)</td>
<td>0.98</td>
</tr>
</tbody>
</table>

* Probability of smoking

Self-reported point prevalence at 8 weeks was 30% in both groups…
Mood and Physical Symptoms

- To assess cigarette withdrawal symptoms
- Information collected repeatedly at baseline, 8 and 24 weeks

### Mood and physical symptoms scale (MPSS) – over the last week

<table>
<thead>
<tr>
<th></th>
<th>Not at all</th>
<th>Slightly</th>
<th>Somewhat</th>
<th>Very</th>
<th>Extremely</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depressed</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Irritable</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Poor concentration</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Disturbed sleep</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Anxious</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

### Urge to smoke in the past week

(1) How much of the time have you felt the urge to smoke in the past week?

<table>
<thead>
<tr>
<th></th>
<th>Not at all</th>
<th>A little of the time</th>
<th>Some of the time</th>
<th>A lot of the time</th>
<th>Almost all the time</th>
<th>All the time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

(2) How strong have the urges been?

<table>
<thead>
<tr>
<th></th>
<th>No urges</th>
<th>Slight</th>
<th>Moderate</th>
<th>Strong</th>
<th>Very Strong</th>
<th>Extremely strong</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

**Strength of Urge to Smoke (SUTS)**
• Total MPSS score and individual withdrawal symptoms were evaluated at 8 and 24 weeks, adjusting for the baselines
  – Linear (MIXED) and Nonlinear Mixed (NLMIXED) models were used to account for correlated data structure
  – GEE (GENMOD) and Generalized Linear Mixed (GLIMMIX) models didn’t work well with more than two categories
    • Assume working correlation structure as independence (TYPE=IND)

• Proportional Odds Regression
  – Fitted on ordinal outcomes (e.g. individual symptoms on a scale of 1-5)
  – Odds were defined as the probability of being in HIGHER levels of the response vs. LOWER levels, e.g. \( \Pr(Y \geq j) / \Pr(Y < j) \) \( j=2,3,4,5 \)
  – An odds ratio of <1 would indicate a positive intervention effect if statistically significant
Smoking Related Outcomes

- No statistically significant differences were observed between the two groups in MPSS total score and individual symptoms.
- Numbers of cigarettes smoked per day was significantly lower in the intervention group (4.75 vs. 5.67; p<0.03).
- Self-rated chance of quitting at 8 weeks was significantly higher in the intervention group (3.96 vs. 3.73; p<0.01).
- Probability of smoking was significantly higher in Maori participants and those with a higher baseline SUTS.
Self-reported levels of physical activity was measured using International Physical Activity Questionnaire (IPAQ):
- An instrument designed primarily for population surveillance of physical activity among adults
- An evaluation tool in intervention studies

It assesses physical activity in the past 7 days across a comprehensive set of domains including:
- work-related physical activity
- transport-related physical activity
- domestic and gardening (yard) activities
- leisure time physical activity

Total PA score is calculated (MET-minutes/week) from each domain as well as:
- walking, moderate, and vigorous PA scores
### IPAQ Outcomes

<table>
<thead>
<tr>
<th>Total PA Score (MET-mins/wk)</th>
<th>Intervention (N=455)</th>
<th>Control (N=451)</th>
<th>*Change from Baseline in Total PA Score</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>Mean</td>
<td>Std</td>
</tr>
<tr>
<td>Baseline</td>
<td>447</td>
<td>6796.91</td>
<td>7849.04</td>
</tr>
<tr>
<td>8 weeks</td>
<td>322</td>
<td>7889.08</td>
<td>8089.41</td>
</tr>
<tr>
<td>24 weeks</td>
<td>287</td>
<td>7049.64</td>
<td>7276.03</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Leisure PA Score (MET-mins/wk)</th>
<th>Intervention (N=455)</th>
<th>Control (N=451)</th>
<th>*Change from Baseline in Leisure PA Score</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>Mean</td>
<td>Std</td>
</tr>
<tr>
<td>Baseline</td>
<td>449</td>
<td>556.57</td>
<td>1094.21</td>
</tr>
<tr>
<td>8 weeks</td>
<td>325</td>
<td>992.02</td>
<td>1461.89</td>
</tr>
<tr>
<td>24 weeks</td>
<td>289</td>
<td>894.7</td>
<td>1673.8</td>
</tr>
</tbody>
</table>

*Repeated Measures Analysis adjusting for baseline outcome and other confounding factors

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**During a typical 7 day period** (a week), how many times on the average do you do the following kinds of **exercise for more than 15 minutes** during your free time?

1. **01** Vigorous exercise (heart beats rapidly) (e.g., running, jogging, hockey, football, soccer, squash, basketball, cross country skiing, judo, roller skating, vigorous swimming, vigorous long distance bicycling)  
   | | Times per week

1. **02** Moderate exercise (not exhausting) (e.g., fast walking, baseball, tennis, easy bicycling, volleyball, badminton, easy swimming, alpine skiing, popular and folk dancing)  
   | | Times per week

1. **03** Mild exercise (minimal effort) (e.g., yoga, archery, fishing from river bank, bowling, horseshoes, golf, snow-mobiling, easy walking)  
   | | Times per week

**Weekly leisure activity score** = (9 x Vigorous) + (5 x Moderate) + (3 x Light)
Main Conclusions

- Compared to usual smoking cessation support from Quitline, the home and telephone-based exercise programme delivered by Green Prescription (in addition to usual care) didn’t show a significant effect in improving abstinence rates and total physical activity in adult smokers trying to quit.

Discussions

- Further investigation on the delivery of interventions (i.e. actual intensity of smoking cessation support provided in both groups)
- Potential trial effect (i.e. the control group were more likely to seek support elsewhere and get involved in exercise)
- Subgroup exploratory analyses
  - Maori (31%) and Pacific (11%) peoples
  - Face-to-face interviewers (24%)
Acknowledgements

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Programme Leader, Physical Activity
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University of Auckland

Joy Jiang
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National Institute for Health Innovation (NIHI)
University of Auckland

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  - Dr Hayden McRobbie (Barts & London School of Medicine and Dentistry, University of London)
  - Vaughan Roberts (NIHI, University of Auckland)
  - Dr Marewa Glover (Center for Tobacco Control Research, University of Auckland)
  - Professor Harry Prapavessis (School of Kinesiology, University of Western Ontario)

• **NIHI Management Committee**: 
  - Sheila Fisher (Finance & Contracts Manager)
  - Michelle Jenkins (Lead Data Manager)
  - Johan Strydom (Senior IT Developer)
Welcome to New Zealand!

Experience

Culture

Nature

Friends

Unwind