Physical exercise or micronutrient supplementation for the wellbeing of the frail elderly? A randomised controlled trial

M J M Chin A Paw, N de Jong, E G Schouten, W A van Staveren, F J Kok

Objective: To examine the effects of 17 weeks of physical exercise and micronutrient supplementation on the psychological wellbeing of 139 independently living, frail, elderly subjects (inactive, body mass index ≤25 or experiencing weight loss).

Methods: Participants (mean (SD) age 78.5 (5.7)) were randomly assigned to: (a) comprehensive, moderate intensity, group exercise; (b) daily micronutrient enriched foods (25–100% recommended daily amount); (c) both; (d) neither. A social programme and identical regular foods were offered as attention control and placebo.

Results: At baseline, moderate to low but significant correlations were found between general wellbeing scores and physical fitness (r = 0.28), functional performance (r = 0.37), and blood concentrations of pyridoxine (r = 0.20), folate (r = 0.25), and vitamin D (r = 0.23) (all p values <0.02), but not with physical activity levels and other blood vitamin concentrations. General wellbeing score and self rated health were not responsive to 17 weeks of exercise or nutritional intervention.

Conclusion: Psychological wellbeing in frail elderly people was not responsive to 17 weeks of intervention with exercise and/or micronutrient enriched foods. The moderate but significant correlations between wellbeing and physical fitness and several blood vitamin concentrations at baseline suggest that changes in wellbeing may occur after long term interventions.

Physical frailty can be defined as a state of reduced physiological reserve associated with an increased susceptibility to disability. In addition to biological aging and chronic diseases, physical inactivity and dietary inadequacies are the main contributors to physical frailty. Because of declines in health, mobility, autonomy, and social contacts, frail older people are at increased risk of a decline in psychological wellbeing. For this reason, they may particularly benefit from preventive interventions related to physical activity and diet.

There is little experimental evidence documenting beneficial effects of exercise on psychological wellbeing in older adults. Existing results suggest that psychological benefits of exercise may only be experienced by depressed or anxious persons. Hypothetical mechanisms by which exercise may mediate psychological wellbeing include physiological explanations such as changes in body temperature, muscular tension, modified brain wave activity, hormonal—for example, catecholamines—or metabolic adaptations, or alterations in the brain monoamines or opioid peptides. Psychosocial explanations include the opportunity of socialising, enhanced feelings of competency and self mastery associated with physical improvements, and distraction of day to day stressors.

Nutritional supplementation is another possible approach to improving feelings of wellbeing. Severe vitamin deficiencies result in dramatic disturbances in behaviour, cognitive functions, emotional state, and personality, but subjects with subclinical vitamin deficiencies also showed behavioural changes such as an increased tendency to depression, irritability, lassitude, and impairment of short term memory. The most common neuropsychiatric manifestation of folate deficiency is depressive symptoms. Because dietary intake is often inadequate in frail elderly people, they are specifically at risk of marginal nutritional status, which may negatively affect their wellbeing.

There is little experimental evidence of the beneficial effects of physical activity or micronutrient supplementation on psychological wellbeing, especially in the elderly, frail or otherwise. Findings have been equivocal, and well controlled studies are scarce. This study was therefore designed to examine the effects of a 17 week comprehensive progressive exercise programme, consumption of enriched foods, or both combined, on the psychological wellbeing of frail elderly subjects. We focused on subjective health, self respect, morale, optimism, and social contacts as aspects of general wellbeing. We hypothesised that an improved fitness and nutritional status would improve psychological wellbeing. The association between changes in physical fitness and biochemical status and changes in wellbeing will also be addressed.

METHODS

Design

The study was a 17 week, randomised, controlled intervention trial with exercise and enriched food products. The two by two factorial design permitted assessment of the effects of both interventions independently, as well as a possible interaction effect. The study protocol was approved by the university medical ethics committee, and written informed consent was obtained from each participant.

Subjects

Volunteers were recruited by personal letter (>7000) sent from senior housing facilities, Meals on Wheels, home care organisations, and general practitioners, flyers posted in senior housing facilities, and advertising in regional/facility newsletters. The following inclusion criteria were screened by

Abbreviations: SSWO, scale of subjective wellbeing for older persons; PASE, physical activity scale for the elderly; BMI, body mass index
telephone: age 70 or older, use of care services—for example, home care, Meals on Wheels—not participating regularly in physical activity of moderate to high intensity, self reported body mass index (BMI) <25 kg/m² or involuntary weight loss, non-institutionalised, no terminal disease or rapidly deteriorating health status, not taking multivitamins for the preceding month, and the ability to understand the study procedures. The 217 eligible subjects were randomly assigned to group a (supervised group exercise; n = 55), group b (enriched food products; n = 58), group c (both; n = 60), or group d (neither; control group; n = 44). Group assignment was by sealed envelopes and took place before baseline measurements. Couples were randomised together. More subjects were assigned to the intervention groups because of an expected higher drop out rate in these groups. Participants were enrolled in the study from January through July 1997.

Exercise intervention
Subjects assigned to exercise participated twice a week for 45 minutes in a standardised, supervised group exercise programme of moderate, gradually increasing intensity. 13 Emphasis was placed on skills training, meaning that the specific activities required for independence in daily activities were practiced. Strength, speed, endurance, flexibility, and coordination training were achieved by performing motor actions such as walking, kneeling, and chair stands. To enhance enjoyment and accessibility, game-like activities were included, and exercises were adjustable to individual mobility levels. To adjust for the effect of socialising and attention, those not randomised to exercise participated in a social programme (lectures, games, crafts) once every two weeks for 90 minutes under the supervision of a creative therapist. The alternative week they were visited at home while being brought a stock of fresh food products. The participants were informed that the effects of either physical or mental activities were evaluated. Participants were asked not to engage in other exercise programmes. Transport to and from all sessions was arranged.

Nutritional intervention
Participants were instructed to eat daily one fruit product, available in two types of juice and compote, and one dairy product, available in vanilla custard, vanilla fruit soft curd cheese, and two types of fruit yogurt. Every week a stock of fresh products (100 g portions, except the cheese, which was in 75 g portions) was delivered to their homes or the exercise/social programme centre. Two enriched products provided on average of 0.5 MJ and about 100% of the Dutch recommended daily amount (RDA) of vitamins D, E, B1, B2, B6, folic acid, B12, and C and about 25–100% of the Dutch RDA of calcium, magnesium, zinc, iron, and iodine. The exercise and control group received identical but non-enriched foods (of similar energy content). The nutritional intervention was a double blind one. Compliance was assessed by measuring the change in a number of serum vitamin levels.

Measurements
Measurements were performed according to a highly standardised protocol, by trained observers who were unaware of the values before intervention. Not all observers could be blinded to exercise or social group assignment because they were often also involved in delivering the products and assisting with the exercising or social programmes. Subjective wellbeing was assessed by the Dutch scale of subjective wellbeing for older persons (SSWO). 17 This scale consists of 30 items divided into five subscales: health (five items), self respect (seven items), morale (six items), optimism (seven items), and contacts (five items). The SSWO sum score indicates general wellbeing. The test-retest reliability coefficient was 0.85. 12 Participants were asked to fill out the questionnaire at home and return it. All items were recoded to 0–2. For each subscale and the sum score, a mean item score was calculated and multiplied by 10, resulting in a range of 0–20 for all subscales and the sum score. A higher score indicates greater wellbeing.

Information on age, marital status, educational level, social contacts, number of friends, diseases, medication, smoking habits, use of care services, and self rated health was collected in a personal interview. Subjective health was measured as general self rated health (1 = very poor health, 10 = excellent health) and health compared with other people of the same age (worse than, the same as, or better than). A question about health compared with before the intervention was included in the questionnaire completed after the intervention. Social involvement was measured as frequency of being contacted and frequency of contacting (visits, phone calls, letters). Physical activity was assessed using a validated questionnaire based on the physical activity scale for the elderly (PASE), slightly adjusted for Dutch elderly. 11,14 A physical fitness score (0–35) was calculated on the basis of the scores on seven components of the validated Groningen fitness test for the elderly 15 := manual dexterity, reaction time, standing balance, flexibility of the hip and spine, shoulder flexibility, hand grip strength, and strength of the right musculus quadriceps femoris. A functional performance score (0–12) was calculated on the basis of six performance criteria: the ability to balance for 10 seconds in tandem stand 16; average usual gait speed and step length over a distance of 6 m without or with a handbag (5 kg) 17; the time required to stand up from a chair 5 times 18; touching the left foot with the right hand and vice versa (in sitting position); putting on and buttoning up a coat. 19 All performance and fitness tests were carried out under standard conditions by the same investigator. For all but one test (the tandem stand, which is scored by using 1 if able, 0 if unable), a score of 0–4 was given, based on sex specific quintiles. A score of 2 denotes an average ability to perform the test; 0 means far below average and 4 means far above average. A performance and fitness score was computed by summing the scores of the individual tests. Higher scores indicate higher fitness or performance.

Weight and height were measured (with the subject in underclothes) and used to calculate BMI.

Fasting blood samples were collected between 0700 and 0900 at the participant’s home and stored at −80°C until analysis. Non-fasting blood samples for determination of ascorbic acid were collected at our research centre at noon; they were immediately put on ice before further processing. Within one hour of collection, the samples for ascorbic acid analysis were deproteinised. Serum pyridoxine and ascorbic acid were determined by high performance liquid chromatography fluorometric detection, serum 25-hydroxyvitamin D by a competitive protein binding assay, erythrocyte thiamine on the basis of transketolase reactivation, and erythrocyte riboflavin on the basis of glutathione reductase reactivation tests. Vitamin B12 and folate concentrations were determined using the ion capture Imx automated immunnoassay system (Abbott Labs, Abbott Park, Illinois, USA). Before and after intervention, samples were analysed in the same run. Biochemical deficiency was defined as one or more blood vitamin concentrations or enzyme activity levels (vitamin D, thiamine, riboflavin, pyridoxine, folate, vitamin B12, ascorbic acid) outside the Dutch reference values.20–25

Statistical analysis
Data were analysed using SAS statistical software, version 6.11 (Statistical Analysis System; SAS Institute Inc, Cary, North Carolina, USA). On the basis of an expected difference between the changes in the intervention groups of 10% with 1 −b = 0.80 and a = 0.05%, a sample size of 26 subjects in each group was needed. Means (SD), medians (10th–90th centiles), or percentages of baseline characteristics were calculated for all four intervention groups. Spearman correlation

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coefficients were calculated between SSWO scores and variables of interest at baseline, and between the 17 week changes in physical fitness scores, functional performance, and blood vitamin concentrations and the 17 week changes in SSWO scores. Differences in SSWO scores between the different categories of sex, marital status, and level of education were tested for significance with the Wilcoxon or Kruskall-Wallis test.

An interaction between the effects of exercise and enriched foods was tested by means of regression analyses with the changes in SSWO scores as a dependent variable, and both interventions and an interaction term as independent variables. Because there was no evidence of an interaction between the two interventions (p = 0.14), the subsequent analysis was performed according to factor (exercise and enriched foods). The average changes for exercise (groups a + c) versus no exercise (groups b + d) and for enriched foods (groups b + c) versus regular foods (groups a + d) were tested by Student’s t test and Wilcoxon rank sum test. p ≤ 0.05 was considered significant.

**RESULTS**

**Drop out rate and compliance**

Of the 217 randomised subjects, 56 (26%) dropped out. The drop out rate was lower in the control group (16%) than in the intervention groups (26–29%). Almost half (25) of drop outs occurred during or immediately after the baseline measures. Reasons given were too much distress and programme too long or at an inconvenient time. The main reasons for drop out during the intervention period were health problems occurred during or immediately after the baseline measure: 30% scored below the norm (13 for men and 11 for women). No significant differences in SSWO were observed according to level of education (low = 13, intermediate = 14, and high = 15, p = 0.33).

**Non-response**

SSWO scores obtained before and after the intervention were available for 139 of the total 161 participants who successfully completed the intervention trial. The main reasons for non-returning the SSWO questionnaire were difficulties with questions and forgetfulness. Other reasons were illness/admission to hospital (n = 3) and refusal (n = 2). Comparing those who returned the questionnaire and those who did not showed that non-responders were on average slightly older (81.2 (4.8)), reported slightly more diseases (2.2 (1.5)), and had a lower education level (50% in the lowest level). Percent-age of men, mean BMI, median number of medicines, and use of care services were similar.

**Baseline characteristics of the participants**

Table 1 presents baseline characteristics of the study participants. Their mean (SD) age was 78.5 (5.7) and about 30% of the participants were men. Almost half of all participants received help with household activities for health reasons, 36% received prepared meals, and 16% received medical assistance. The exercise group (group a) was significantly younger than the other groups.

**Psychological wellbeing**

Table 2 shows the median SSWO scores and the mean 17 week changes according to type of intervention: exercise (groups a+c) versus no exercise (groups b+d) and nutrient enriched (group b+c) versus regular foods (groups a+d). Baseline median SSWO scores were 13 out of a 20 point maximum, and 30% scored below the norm (13 for men and 11 for women). Median SSWO scores were higher in men than in women (15 and 13 respectively, p = 0.003), and higher in married than in widowed subjects (15 and 12 respectively, p = 0.01). Divorced and single subjects scored in between (14). No significant differences in SSWO were observed according to level of education (low = 13, intermediate = 14, and high = 15, p = 0.33).

Table 1  Baseline characteristics of the study population according to intervention group (n=139)

<table>
<thead>
<tr>
<th></th>
<th>Exercise (group a) (n=35)</th>
<th>Enriched foods (group b) (n=38)</th>
<th>Both (group c) (n=32)</th>
<th>Control (group d) (n=34)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>76.1 (4.3)*</td>
<td>79.6 (4.9)</td>
<td>79.4 (6.1)</td>
<td>78.7 (6.6)</td>
</tr>
<tr>
<td>Male [%]</td>
<td>26</td>
<td>29</td>
<td>25</td>
<td>32</td>
</tr>
<tr>
<td>Marital status [%]</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>37</td>
<td>32</td>
<td>38</td>
<td>32</td>
</tr>
<tr>
<td>Widowed</td>
<td>54</td>
<td>53</td>
<td>50</td>
<td>56</td>
</tr>
<tr>
<td>Divorced</td>
<td>9</td>
<td>5</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td>Never married</td>
<td>–</td>
<td>11</td>
<td>9</td>
<td>6</td>
</tr>
<tr>
<td>Education [%]†</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>40</td>
<td>25</td>
<td>37</td>
<td>41</td>
</tr>
<tr>
<td>Intermediate</td>
<td>40</td>
<td>56</td>
<td>47</td>
<td>47</td>
</tr>
<tr>
<td>High</td>
<td>20</td>
<td>19</td>
<td>16</td>
<td>12</td>
</tr>
<tr>
<td>Number of real friends</td>
<td>3 (0–6)</td>
<td>3 (0–7)</td>
<td>3 (0–6)</td>
<td>1 (0–5)</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>24.4 (3.0)</td>
<td>24.4 (2.5)</td>
<td>25.2 (2.3)</td>
<td>24.2 (3.2)</td>
</tr>
<tr>
<td>PASE score [0–400]**</td>
<td>63 (27–100)</td>
<td>59 (34–103)</td>
<td>58 (34–93)</td>
<td>59 (27–117)</td>
</tr>
<tr>
<td>Number of medications‡</td>
<td>2 (0–6)</td>
<td>2.5 (0–5)</td>
<td>3 (0–5)</td>
<td>3 (0–7)</td>
</tr>
<tr>
<td>Number of self reported diseases</td>
<td>1.7 (0.9)</td>
<td>1.9 (1.2)</td>
<td>1.8 (1.0)</td>
<td>1.9 (1.4)</td>
</tr>
<tr>
<td>Use of care services for health reasons [%]</td>
<td>29</td>
<td>39</td>
<td>47</td>
<td>32</td>
</tr>
<tr>
<td>Meals on Wheels</td>
<td>40</td>
<td>50</td>
<td>47</td>
<td>35</td>
</tr>
<tr>
<td>Household assistance</td>
<td>14</td>
<td>21</td>
<td>16</td>
<td>15</td>
</tr>
</tbody>
</table>

Where applicable, values are mean (SD).

*Significantly different from the control group; †low = primary or lower vocational training, intermediate = intermediate vocational or higher general training, high = higher vocational or university training; ‡median (10th–90th centile).

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However, participants with financial difficulties scored significantly lower than participants with infrequent or no financial difficulties (14 v 11, p = 0.04). Median SSWO scores were also lower in drop outs (12 v 13, p = 0.02; data not shown).

Table 3 shows the correlation coefficients between SSWO scores and indicators of health and nutritional status at baseline. Baseline SSWO scores correlated positively with self rated health (r = 0.40, p = 0.0001), fitness scores (r = 0.28, p = 0.001), functional performance score (r = 0.37, p = 0.0001), and serum pyridoxine (r = 0.20, p = 0.02), folate (r = 0.25, p = 0.003) and vitamin D (r = 0.23, p = 0.01) concentrations. No significant correlation was observed between SSWO scores and age, number of friends, activity scores, number of diseases or medications, BMI, transketolase, and glutathione reductase activity (as measures of thiamine and riboflavin respectively), and concentrations of ascorbic acid and vitamin B12.

Median SSWO scores had not changed significantly after 17 weeks of intervention. The number of participants scoring below the norm declined by 3% in the exercising group and concentrations of ascorbic acid and vitamin B12.

DISCUSSION
In this study, SSWO scores as a measure of psychological wellbeing were not responsive to 17 week interventions with exercise or enriched foods in a group of frail older people. However, both interventions were positively evaluated, well tolerated, and effective in improving functional performance, physical fitness, and reversing micronutrient deficiencies.26–28

Well controlled studies on the effects of exercise and micronutrient supplements on psychological wellbeing are scarce, and the available data are equivocal.4–13 Our findings are in concordance with those of Blumenthal et al29 and Swoap et al,30 who found no significant improvement in the psychological wellbeing of men and women older than 60 years of age after 16 weeks of aerobic activity or yoga/flexibility exercises (n = 97) and 26 weeks of high or moderate intensity aerobic exercise (n = 49) respectively. Both studies examined healthy...
elderly subjects. Frail elderly people are likely to experience lower psychological wellbeing because of declines in health, mobility, autonomy, social contacts, and nutritional status. They may therefore experience greater gains in wellbeing from improved physical fitness and nutritional status. Indeed, SSWO scores at baseline correlated significantly with physical fitness, performance, and blood pyridoxine, folate, and vitamin D concentrations, but not with physical activity level and other blood vitamin levels. The correlations were, however, moderate to low. No relation between changes in physical fitness, performance, and biochemical vitamin status on the one hand and changes in SSWO scores on the other hand was observed.

This is, to our knowledge, the first controlled trial examining the effects of the consumption of foods enriched with a physiological dose of several micronutrients on the wellbeing of frail elderly people. Bunker et al. observed a significant improvement in wellbeing in 12 weeks in both a multinutrient supplemented (a high protein dairy drink containing vitamins and macronutrients and a capsule containing a mixture of trace elements) and placebo (starch containing capsule) group of frail, housebound, elderly people, with an even greater improvement in the control group. This suggests that the improvement was not due to the supplement but to the effects of socialising and attention. Moreover, the importance of an appropriate control group is emphasised. Smidt et al. observed significantly increased wellbeing after six weeks of thiamine supplementation in healthy elderly women with a marginal thiamine deficiency compared with baseline and placebo supplemented values. In our study the supplementation dose (1 mg v 10 mg thiamine a day) and prevalence of thiamine deficiency (14% v 48%) were much lower. Nonetheless, the amount and duration of supplementation we used were effective in increasing blood vitamin levels. The difference in measures of psychological wellbeing complicates comparison between studies.

One explanation for the lack of effects may be that the outcome measure chosen to assess subjective wellbeing is not sensitive to change, despite significant changes in objective measures such as physical fitness score, functional abilities, and biochemical values. Indeed, many participants reported that they enjoyed programme participation and the contacts with the researchers and other participants very much, suggesting improved wellbeing. We observed a lower SSWO score among widowers and among those with lower fitness scores, blood vitamin levels, self rated health, educational levels, and financial problems. The SSWO score can thus be used to classify the elderly into categories of wellbeing but may be less suitable as an effect measure in intervention studies.

Another possibility is that subjective wellbeing may be a fairly stable concept which is rather insensitive to change, particularly at an older age. Studies on subjective health (one aspect of wellbeing) suggest that older people adapt to deterioration in health and functional status by changing their expectations and norms, resulting in a decreasing association between functional status and self rated health with increasing age. Health appraisals at an older age may be more based on attitudes and health habits than on medical and functional factors. A similar finding was reported in a study by Ardelt, who suggested that wisdom, a person's degree of psychosocial development, has a stronger influence on life satisfaction than objective life conditions such as improved fitness and nutritional status. Another possible mechanism explaining the stability in subjective wellbeing are social comparisons. In a study by Heidrich and Ryff, the effects of social comparisons appeared to be strongest for women in the poorest health, resulting in psychological outcomes similar to women in good health.

A third possibility is that the degree of frailty was not severe enough to result in psychological distress. Our study focused on frail but still independently living elderly people. We used a need for care services (home care, Meals on Wheels), physical inactivity (no regular exercise), and involuntary weight loss or a BMI below average as the main selection criteria. Inactivity in combination with weight loss seems to be an effective screening criterion for identifying frailty among a non-institutionalised elderly population group. Indeed our study population was on average less healthy and active than the average healthy elderly Dutch population; self rated health (7.0 v 7.7), activity level (67.6 v 71.9 for men, 64.6 v 97.9 for women), physical fitness, and functional performance were all below average. Indicators of nutritional status were below average as well: the mean BMI of 24.5 kg/m² was lower than that of the Dutch healthy elderly population (26.2 for men and 28.2 for women), and blood vitamin deficiency varied between 42% for vitamin B12 and 39% for vitamin D to 3% for vitamin B2 (as measured by erythrocyte glutathione alpha). In addition, the percentage of participants scoring below the norm for SSWO was higher than in the normal population (30% v 11%).

At baseline, the exercise group (group a) was slightly younger than the other groups. For the analysis, the two exercising groups (groups a + c) were compared with the two non-exercising groups (groups b + d) making the age difference between groups smaller and not significant. Adjusting for age did not change the results.

In conclusion, psychological wellbeing in frail elderly people was not responsive to 17 weeks of intervention with exercise and/or micronutrient enriched foods despite a significant increase in physical fitness and blood vitamin concentrations. The moderate but significant correlations between wellbeing and physical fitness and several blood vitamin concentrations...

| Table 4 Subjective health and social contacts of the study population at baseline and after 17 weeks of intervention (n=139) |
|-------------------------------------------------|-------------------------------------------------|-------------------------------------------------|-------------------------------------------------|-------------------------------------------------|
|                                                  | Exercise (group a+c) (n=67)                      | No exercise (group b+d) (n=72)                   | Enriched foods (group a+c) (n=70)                | Regular foods (group a-d) (n=69)                   |
| Subjective health                                |                                                  |                                                  |                                                  |                                                  |
| Self rated health [1-10]†                         | 6.9 (1.2)                                       | 6.9 (1.5)                                       | 6.9 (1.5)                                       | 6.9 (1.3)                                       |
| change                                          | -0.2 (1.0)                                      | 0.1 (1.2)                                       | -0.2 (1.0)                                      | 0.2 (1.3)                                       |
| % feeling healthier than same aged              | 66                                              | 60                                              | 60                                              | 57                                              |
| change                                          | 1                                               | 1                                               | 1                                               | 1                                               |
| % feeling healthier than before intervention     | 28                                              | 13                                              | 14                                              | 26                                              |
| Social involvement                              |                                                  |                                                  |                                                  |                                                  |
| % being contacted ≤2 weeks change                | 21                                              | 24                                              | 20                                              | 25                                              |
| % contacting others ≤2 weeks change              | -5                                              | -3                                              | 6                                               | -9                                              |
| change                                          | 33                                              | 42                                              | 39                                              | 37                                              |
| % contacting others ≤2 weeks change              | -9                                              | -15                                             | -12                                             | 13                                              |

Numbers vary slightly because of missing data. †Values are mean (SD).
Does wellbeing respond to exercise or micronutrients?

Take home message

Perceived psychological wellbeing in frail older people is not responsive to 17 weeks of physical exercise or dietary supplements. Is wellbeing a stable concept or are existing measures not responsive to subtle changes?

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Authors’ affiliations

M J M Chin A Paw, N de Jong, E G Schouten, W A van Staveren, F J Kok, Division of Human Nutrition and Epidemiology, Wageningen University, The Netherlands

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