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*Clinical Article*

# Mild traumatic brain injuries: the impact of early intervention on late sequelae. A randomized controlled trial

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## Summary

*Background*. Positive results from early clinical intervention of mild traumatic brain injury (MTBI) patients by rehabilitation specialists have been reported. Various treatments have been used, but few controlled studies are published. We hypothesised that early rehabilitation of selected MTBI patients would reduce long term sequelae.

*Method*. A randomised controlled trial with one year follow-up. Among 1719 consecutive patients with MTBI, 395 individuals, 16–60 years of age, met the MTBI definition. Exclusion criteria were: previous clinically significant brain disorders and/or a history of substance abuse. The control group ($n = 131$) received regular care. The intervention group ($n = 264$) was examined by a rehabilitation specialist. 78 patients were mainly referred to an occupational therapist. The problems were identified in daily activities and in terms of post-concussion symptoms (PCS), an individualised, tailored treatment was given. Primary endpoint was change in rate of PCS and in life satisfaction at one-year follow-up between the groups.

*Findings*. No statistical differences were found between the intervention and control groups. Patients who experienced few PCS two to eight weeks after the injury and declined rehabilitation recovered and returned to their pre-injury status. Patients who suffered several PCS and accepted rehabilitation did not recover after one year.

*Interpretation*. In this particular MTBI sample, early active rehabilitation did not change the outcome to a statistically-significant degree. Further studies should focus on patients with several complaints during the first 1–3 months and test various types of interventions.

*Keywords:* Mild traumatic brain injuries; post-concussion symptoms; randomised controlled trial; rehabilitation.

## Introduction

The annual rates of mild traumatic brain injuries (MTBI) [25] are reported to be 130–546 per 100,000 persons [2, 4, 26]. About 10% have symptoms more than one year after injury [42, 44]. The prevalence of individuals with more or less permanent sequelae after MTBI in a Swedish population could be estimated at about 1% [44]. In patients with post-concussion symptoms (PCS) one year after MTBI, psychological well-being and health-related quality of life are also reported to be impaired [15, 23, 42]. Some patients may not become aware of, or admit, the extent of their symptoms until an attempt is made to return to normal functioning [18].

Encouraging results from systematic follow-ups of MTBI by rehabilitation specialists have been reported and suggest that early clinical intervention would be

beneficial, as follow-up after discharge would minimise losses in social well-being [41, 52].

Previous studies have also shown that many MTBI patients recover without any intervention [27, 29].

Nevertheless, recommendations have been made that all MTBI patients should be offered a visit to a specialist early after injury in order to explore the need for active rehabilitation [46, 53]. It has been emphasized that controlled studies are required [12] and should limit their focus in order to reduce the impact of confounding factors. Therefore we designed this study to test the hypothesis that a program of early and active management of patients with an uncomplicated MTBI presenting to hospital services would reduce late sequelae.

## Methods

The study tested the hypothesis that a program of early and active management of patients with an uncomplicated MTBI, utilizing existing hospital services would: 1. reduce the number of post-concussion symptoms; 2. result in better life satisfaction and health-related quality of life; 3. result in better outcome as regards community integration into home and family life, social activity, productive activity, interests and leisure time.

The Ethics Committee at Göteborg University approved the study. All patients received a leaflet explaining its purpose and those who participated gave oral consent.

### *Participants*

Study participants were recruited at the Södra Älvsborgs Hospital (population: 182,648, 31 December 2000). This area, the Southern Alvsborg County, is a mixed urban and rural area in the southwest region of Sweden. The enrolment period lasted from 6 September 1997 to 30 September 2000. The one-year follow up was closed 31 December 2001.

The inclusion criteria were: being 16–60 years of age and satisfying the definition for a mild traumatic brain injury by the American Congress of Rehabilitation Medicine (footnote) (Mild Traumatic Brain Injury Committee 1993) [25].

### *Footnote*

The definition of MTBI according to the Mild Traumatic Brain Injury Committee of the Head Injury Interdisciplinary Special Interest Group of the American Congress of Rehabilitation Medicine [25] is as follows: ''A patient with mild traumatic brain injury is a person who has had a traumatically induced physiological disruption of brain function, as manifested by at least one of the following: 1. any period of loss of consciousness; 2. any loss of memory for events immediately before or after the accident; 3. any alteration in mental state at the time of the accident (e.g., feeling dazed, disorientated, or confused); and 4. focal neurological deficit(s) that may not be transient, but where the severity of the injury does not exceed the following: – loss of consciousness of approximately 30 minutes or less; – after 30 minutes, an initial Glasgow Coma Scale of 13–15; and – posttraumatic amnesia not greater than 24 hours.''

Patients were excluded on the following criteria: previous clinically significant brain disorders (earlier brain injury, psychiatric disease, and mental retardation), a history of substance abuse, language difficulties (non-native Swedish speakers) and not resident in the catchment area. In addition, patients were excluded if notified more than two months after the registered injury.

### *Data set up*

The physicians on call were requested to use a specially designed head injury form for all attendees treated as brain concussion patients at the Accident and Emergency Unit of the Department of General Surgery. To ensure that the MTBI Register would include all eligible patients every week the study secretary searched the register of the Accident and Emergency Unit for current diagnoses according to the International Classification of Diseases (ICD-10) [22] (S060–S069, S097–S099, S020–S029).

### *Sample size*

On the basis of clinical experience confirmed by two pilot studies [3, 14], we considered that a 15% reduction of the post-concussion symptoms (the primary endpoint) would be a clinically relevant effect and the sufficient total number of patients would be 384.

### *Randomization*

The randomization was done in the proportion 2:1 (rehabilitation group: control group) in order to get more

information from the rehabilitation treatment and to assess more patients to what is assumed to be the best treatment, with only a minor loss in power [39].

The patient was allocated to either the intervention group or controls by the automatic randomization procedure using the method introduced by Pocock [38, 40] for optimized allocation. The two groups were balanced according to the following ten variables (age, gender, loss of consciousness, amnesia, acute ethyl intoxication, focal neurology, dizziness, headache, vomiting, and nausea), which in a preliminary study [14] were found a statistical significant correlation between the outcome variables PCS and Short Form Health Survey, SF-36.

Blinding of outcome assessment was effected by using mailed questionnaires for self-rating; the data thus collected were entered by a secretary having no information of the allocation and then sent to the statisticians. All the patients in the intervention and the control group were sent two questionnaires the first questionnaire two to eight weeks (median three weeks) after the injury to collect information about the individual's pre-injury conditions (marital status, education, employment, unemployment and being on sick list) and outcome variables. The second questionnaire to evaluate the effects of intervention was sent regarding all outcome variables one year after the injury.

*Interventions*

All patients continued to have access to existing hospital services, although local clinical services normally do not include routine follow-up of patients after an uncomplicated head injury.

Patients randomized to the intervention group ($n = 264$) were contacted by telephone at 2–8 weeks (median 3 weeks) after injury. The alternative approach was by letter ($n = 50$). Patients feeling unwell because of post-concussion symptoms were offered an appointment at the Department of Rehabilitation Medicine. A rehabilitation specialist (RB) examined 96 patients. After assessment of their history and symptoms, a routine examination was performed. If considered as MTBI patients with post-concussion symptoms, they received oral information, counselling, encouragement, and assessment of the need for pharmaceutical therapy (i. a. for pain, depression, sleep disturbances). Outpatient appointments (mean 1, range 1–5) and telephone contacts (mean 6, range 1–14) were carried out. If required, patients were mainly referred to occupational therapist, social worker, physiotherapist and other medical specialists. 78 patients were referred to an occupational therapist (EEA). Problems were identified in daily activities and regarding post-concussion symptoms. Individualized treatment was started and the aim was, first, to reassure the patients that problems post injury were common and would probably disappear within a few months, second, to help the patients master the post-concussion symptoms and manage their daily activities. Appropriate coping strategies were proposed and a written schedule was introduced to structure daily activities in order to balance the efforts needed. A diary was introduced to patients with memory problems.

Patients had repeated outpatients' appointments (mean 5, range 1–15) every week for the first weeks and thereafter telephone contacts (mean 10, range 1–20). Visits at work or at school were included if required and home calls were carried out to inform about the circumstances after the MTBI. Ergonomic counseling and relaxation techniques were introduced.

*Outcome variables*

For evaluation of the effects of intervention, the study was designed to compare the intervention group with control group except the SF-36 which was compared with a Swedish reference group, regarding the outcome variables one year after the injury [49, 50].

For the primary effect variables following instruments were used.

1. The Post-Concussion Symptoms Questionnaire (PCSQ) used in a preliminary study [3, 14] including 21 items (cf Table 2).
2. The Life Satisfaction Questionnaire (LiSat-11) [16], a checklist used for reporting perceived life satisfaction in eleven specific domains where each item is checked along a six-grade scale.

For evolution of the secondary effect variables following instruments were used.

3. The Community Integration Questionnaire (CIQ), Swedish version [19, 54], designed to quantify an individual's integration into home and family life, social activity, and productive activity. It is based on 15 questions within these areas that an individual would normally expect to perform.
4. The Short-Form Health Survey (SF-36) [53], quantifying bodily and mental aspects by self-rating eight health domains: physical functioning, social functioning, role functioning-physical, bodily pain, mental health, role functioning-emotional, vitality (energy and fatigue), and general health perception. The

Swedish version has been translated into Swedish using methods later adopted by International Quality of Life Assessment (IQOLA) project procedures. The percentage of subjects from whom scale scores were computable were consistently high (above 90%) matching the U.S. values. The items raw scores are coded, summed across items in the same scales cores are transformed into a 0–100 scale, a higher value refer to a better health [49, 50].

For evaluation of the effects of intervention between intervention and control groups before one year after the injury, following instruments were used.

5. The Swedish version [7] of the Interest Checklist [28], assessing interests in 50 activities in the five areas: manual activities, activities sports, social activities, recreation, daily activities and cultural activities. In the analyses 39 of the 50 activities were grouped into 15 subgroups.
6. A modified Swedish version [8] of the Role Checklist developed by Oakley *et al.* [32], ranking participation in ten different occupational roles.
7. The Job Satisfaction Checklist by Simovici [45] in a Swedish version by Branholm [7] quantifying job satisfaction.

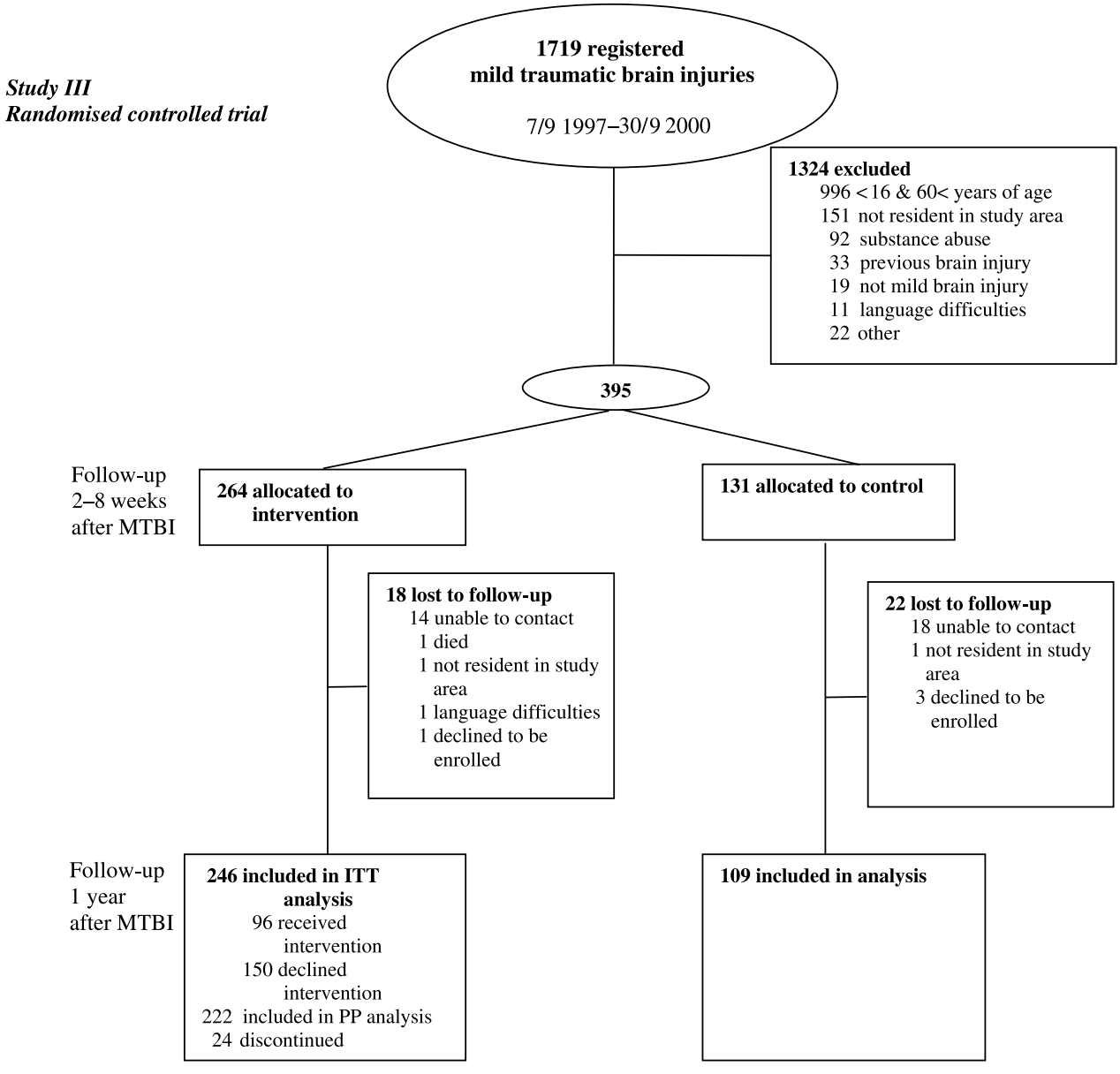


Fig. 1. Participant flow through the trial

*Statistical methods*

For comparisons between groups, Fisher's non-parametric permutation test [17, 33] was used for ordered and continuous variables. The test is non-parametric, the test statistic uses the original values and not only the ranks, when distribution is ''near'' the normal distribution the test can be shown to be uniformly most powerful, while Fisher's exact test was used for dichotomous variables [33]. Changes over time for dichotomous and ordered variables were categorised only as worse, equal and improved and they were thus analysed with the sign test within groups and with Mantel Haentzel's chi-squared test between groups. Changes over time for continuous variables were analysed with Fisher's non-parametric permutation test for matched pairs [17]. The distribution of ordinal variables was given as the median and range, while the distribution for continuous variables was given as the number, mean, median, standard deviation (SD) and range. All significance tests were conducted at the 5% significance level. Due to the multiplicity problem, the upper limit for the number of false significances is given where appropriate.

Additional per protocol analyses were performed. The definition of per protocol group was all the randomised patients who continued the intervention according to the programme designed for this study [21].

Table 1. *Demographic data of patients*

| Characteristic | Intervention group ($n = 264$) | Control group ($n = 131$) | $p$-Value |
|---|---|---|---|
| *Age* | | | |
| – Mean (SD), | 32 (12.6) | 34 (12.5) | 0.23 |
| – Median (range) | 29 (16–58) | 32 (16–59) | |
| *Sex* | | | |
| – Male | 157 (59) | 88 (67) | 0.17 |
| – Female | 107 (41) | 43 (33) | |
| *Marital status* | | | |
| – Single adult | 95 (41) | 40 (40) | |
| – Married/cohabiting | 126 (54) | 50 (50) | |
| – Divorced/widowed/ separated | 13 (6) | 11 (11) | 0.22 |
| *Employment* | | | |
| – Student | 44 (17) | 19 (15) | 1.0 |
| – Employed | 149 (64) | 66 (66) | 0.78 |
| – Unemployed | 17 (6) | 6 (5) | ND |
| – Full time housework | 8 (3) | 2 (2) | ND |
| – Retired | 7 (3) | 2 (2) | ND |
| – Other | 7 (3) | 2 (2) | ND |
| – Sick certificates at injury | 6 (8) | 7 (22) | 0.09 |
| *Accident type* | | | |
| – Road traffic accident | 63 (24) | 33 (25) | |
| – Fall downwards | 48 (18) | 26 (20) | |
| – Fall on the ground | 70 (27) | 32 (24) | |
| – Blow | 66 (25) | 33 (25) | |
| – Unknown | 17 (6) | 7 (6) | 0.95 |
| *Data on hospital admission* | | | |
| – Unconsciousness at injury | 117 (45) | 58 (44) | 0.97 |
| – Amnesia | 155 (61) | 75 (59) | 0.75 |
| – Ethyl | 58 (22) | 27 (21) | 0.91 |
| – Focal neurology | 10 (4) | 7 (6) | 0.66 |
| – Dizziness | 60 (24) | 39 (32) | 0.29 |
| – Headache | 146 (61) | 63 (52) | 0.12 |
| – Vomiting | 26 (11) | 15 (12) | 0.89 |
| – Nausea | 88 (37) | 15 (12) | 1.00 |
| – RLS 1 | 213 (87) | 109 (89) | 0.45 |
| *Post traumatic amnesia as estimated at one year follow up* | | | |
| – No amnesia | 34 (25) | 18 (31) | |
| – <30 min | 59 (42) | 22 (37) | |
| – 30 min–6 hours | 38 (27) | 12 (20) | |
| – 6–24 hours | 5 (4) | 4 (7) | |
| – >24 hours | 3 (2) | 3 (5) | 0.09 |

*RLS* Reaction Level Scale [47, 48]; *ND* not done; no statistical test performed.

## Results

Figure 1 shows the patient flow through the trial.

One year after the injury, 355 patients were followed up: 246 in the intention-to-treat (ITT) intervention group and 109 in the control group. However, as 24 participants discontinued the intervention due to: psychosocial

Table 2. *Post-concussion symptoms (PCS) one year after injury*

| Post-concussion symptoms (PCS), n (%) | Intervention group ($n = 226$) | Control group ($n = 101$) | $p$-Value differences |
|---|---|---|---|
| Extremity weakness | 50 (22) | 22 (22) | NS |
| Sensitivity to noise | 56 (25) | 21 (21) | NS |
| Hard of hearing | 33 (15) | 12 (12) | NS |
| Sensitivity to light | 44 (20) | 15 (15) | NS |
| Visual impairment | 59 (27) | 26 (26) | NS |
| Anosmia | 15 (7) | 2 (2) | 0.035 |
| Dizziness | 69 (31) | 29 (29) | NS |
| Language difficulties | 56 (25) | 16 (16) | NS |
| Orientation problems | 10 (4) | 6 (6) | NS |
| Decreased simultane capacity | 37 (17) | 14 (14) | NS |
| Fatigue | 90 (41) | 27 (27) | NS |
| Poor concentration | 72 (32) | 25 (25) | NS |
| Poor memory | 61 (27) | 22 (22) | NS |
| Irritability | 79 (35) | 25 (25) | NS |
| Anxiety | 64 (28) | 22 (22) | NS |
| Emotional lability | 62 (28) | 20 (20) | NS |
| Depression | 78 (35) | 30 (30) | NS |
| Sleep disturbances | 37 (17) | 20 (20) | NS |
| Headache | 93 (42) | 34 (34) | NS |
| Neck pain | 78 (35) | 42 (42) | NS |
| No symptoms | 61 (27) | 32 (32) | NS |
| Number of symptoms | | | |
| Mean (SD) | 5.2 (5.3) | 4.4 (5.3) | NS |
| Median (range) | 4 (0–20) | 2 (0–20) | |

Table 3. *Life satisfaction checklist (LiSat-11) one year after injury for three items*

| | Physical health (%) | | | Leisure, *n* (%) | | | Financial, *n* (%) | | |
|---|---|---|---|---|---|---|---|---|---|
| | Intervention group, intention-to-treat | Intervention group, per protocol | Control group | Intervention group, intention-to-treat | Intervention group, per protocol | Control group | Intervention group, intention-to-treat | Intervention group, per protocol | Control group |
| Very satisfied | 58 (26)* | 56 (28) | 27 (27) | 46 (20) | 43 (22)* | 21 (21) | 17 (7) | 17 (9)* | 6 (6) |
| Satisfied | 70 (31)* | 65 (33) | 30 (30) | 78 (35) | 71 (36)* | 29 (29) | 55 (24) | 53 (27)* | 25 (25) |
| Rather satisfied | 53 (23)* | 44 (22) | 21 (21) | 68 (30) | 58 (30)* | 26 (26) | 83 (37) | 76 (39)* | 32 (32) |
| Rather dissatisfied | 24 (11)* | 19 (10) | 2 (2) | 19 (8) | 15 (8)* | 11 (11) | 34 (15) | 26 (13)* | 14 (14) |
| Dissatisfied | 15 (7)* | 9 (5) | 13 (13) | 10 (4) | 7 (4)* | 7 (7) | 15 (7) | 13 (7)* | 10 (10) |
| Very dissatisfied | 6 (3)* | 4 (2) | 8 (8) | 4 (2) | 2 (1)* | 5 (5) | 22(10) | 12 (6)* | 13 (13) |

* $p$-Value $< 0.05$ compared with control groups.

circumstances ($n = 12$), concurrent somatic diseases ($n = 7$) or to psychiatric disorders ($n = 5$), The per protocol (PP) analysis included 222 participants. The intervention group and the control group were comparable in terms of demographic data and injury severity (Table 1). In the intervention group there were 150 patients who declined treatment, they were analysed in the intervention groups and compared with the control group.

The principal reason for patients to decline treatment ($n = 150$) was that they stated that their health had been restored to previous health in the telephone follow-up two to eight weeks (median three weeks) after the MTBI.

The total loss to follow-up was 40 of 395 patients (10%), 18 of 264 (7%) in the intervention group and 22 of 131 (17%) in the control group.

Comparison of data between the intention-to-treat (ITT) and control group collected at the one-year follow-up.

ITT analyses (246 patients). In the ITT analysis, the data for the intervention group revealed no statistically-significant differences in the primary effect variables, defined by the PCSQ (Table 2) and LiSat-11 (Table 3) apart from the single item of ''physical health'', where there was a statistically-significant higher score.

The secondary effect variables the CIQ (Table 4) and the SF-36 (Fig. 2) (Table 5) did not reveal any differences between the intervention group and the control group.

All the MTBI patients obtained statistically-significantly ($p < 0.05$) lower scores than the Swedish reference group in all the SF-36 domains (Fig. 2) (Table 5).

### *Additional analyses*

In the per protocol (PP) analysis of the LiSat-11, the intervention group displayed no statistically-significant improvement, apart from the items of ''leisure'' and ''financial'' (Table 3). In the analyses of LiSat 11, there were three items which had a higher score to a statistically-significant degree, one for the ITT group and two

Table 4. *Community Integration Questionnaire (CIQ) one year after injury*

| | Mean (SD)<br>Median (range) | | |
|---|---|---|---|
| | Intervention group | Control group | |
| Home Integration | 5.7 (2.9)<br>5 (0–10) | 5.5 (3.0)<br>5 (0–10) | 5* |
| Social Integration | 9.1 (1.9)<br>9 (4–12) | 8.7 (2.1)<br>9 (2–12) | 9* |
| Productivity | 5.5 (1.4)<br>6 (0–7) | 5.6 (1.5)<br>6 (0–7) | 6* |
| CIQ total | 20.3 (4.0)<br>20 (8–29) | 19.8 (4.0)<br>20 (11–28) | 20* |

* Patients without traumatic brain injury; non-disabled adults.
References: Willer *et al.* [54], Hall *et al.* [19].

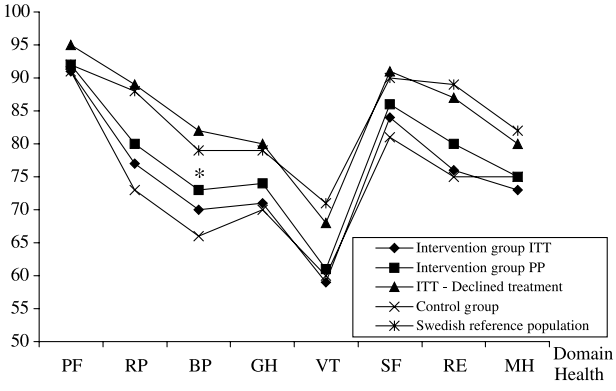


Fig. 2. Short Form Health Survey (SF-36) one year after injury. *PF* Physical functioning; *RP* role physical; *BP* bodily pain; *GH* general health; *VT* vitality; *SF* social functioning; *RE* role emotional; *MH* mental health; *ITT* intention to treat; *PP* per protocol. *$p$-Value $< 0.05$ 0.05 for the item of bodily pain in the intervention group in the PP analyses

Table 5. *SF-36, means and confidence interval (CI)*

| | ITT intervention group ($n=226$) | | Control group ($n=101$) | | ITT declined treatment ($n=150$) | | Swedish reference group [49] ($n=8930$) | |
|---|---|---|---|---|---|---|---|---|
| Items | mean | CI* | mean | CI* | | | mean | CI* |
| Physical functioning | 90.6 | 88.3–92.8 | 90.6 | 87.6–93.6 | 94.7 | 92.2–97.3 | 87.9 | 87.5–88.3 |
| Role physical | 77.1 | 72.6–81.6 | 72.5 | 65.3–79.7 | 88.6 | 84.1–93.0 | 83.2 | 82.5–83.8 |
| Bodily pain | 70.4 | 66.7–74.0 | 66.2 | 60.1–72.2 | 82.0 | 77.3–83.7 | 74.8 | 74.3–75.4 |
| General health | 70.7 | 67.4–55.2 | 70.1 | 65.1–75.1 | 82.0 | 76.3–83.7 | 75.8 | 75.4–76.3 |
| Vitality | 58.5 | 55.2–61.8 | 59.8 | 55.0–64.5 | 67.6 | 63.5–71.6 | 68.8 | 68.3–69.3 |
| Social functioning | 84.1 | 81.2–87.1 | 81.2 | 76.1–86.3 | 91.0 | 87.8–94.1 | 88.6 | 88.2–89.0 |
| Role emotional | 76.2 | 71.5–81.0 | 74.9 | 67.4–82.4 | 87.4 | 82.4–92.3 | 85.7 | 85.0–86.3 |
| Mental health | 73.1 | 70.3–75.8 | 75.1 | 70.8–79.4 | 80.3 | 77.2–83.4 | 80.9 | 80.5–81.3 |

SF-36 scores are transformed to a 0–100 scale. A higher score indicate better health. * 95% confidence interval. *ITT* Intention-to-treat.

for the PP group. One of these items could be a false significance.

In the PP analyses of the SF-36, one item ''bodily pain'' revealed higher score and a statistically-significant degree, ($p<0.05$) significant, but this could also be a false significance (Fig. 2).

### *Comparison of data before injury and one year after injury*

The Interest Checklist revealed statistically-significantly decreased activities for seven of the 15 grouped items for the intervention group and for two items for the control group. The Role Checklist revealed, ''increased activity'' for the categories of ''students'' and ''participants in organisations'' in the intervention group, as well as increased activity for ''students'' in the control group. The Job Satisfaction Checklist revealed a statistically-significant impairment for ''recognition at work'' for the intervention group and no changes at the one-year follow-up for the control group.

In the analyses before and after the MTBI, there could be one (or two) false significance for the instruments Interest Checklist, Role Checklist and Job Satisfaction Checklist.

## Discussion

### *Key findings*

The results indicate that early individual intervention by a qualified rehabilitation team, for patients with symptoms related to MTBI, does not appear to change the consequences one year after injury, compared with a non-intervention group. The rehabilitation started within two to eight weeks (median three weeks) for patients with MTBI but with no known significant previous brain disorder or any history of substance abuse. There were no statistically-significant differences between the intervention group and the control group: in terms of PCS, life satisfaction, health-related quality of life, and community integration into home and family life, social activity, productivity activity and leisure time. The LiSat-11 instrument revealed a statistically-significant improvement for a single item, ''physical health''. The patients in the intervention group who declined ($n=150$) intervention had the same number of symptoms one year after the injury as before the injury and the same or higher SF-36 scores than the Swedish reference group.

### *Explanations*

The explanation of these results may simply be that about half of the selected group of MTBI patients, i.e. those with few complaints at the telephone follow-up two to eight weeks (median three weeks) after the MTBI, has recovered spontaneously within a period of one year. Patients with more complaints at two to eight weeks (median three weeks) after injury who participated in early rehabilitation did not recover after one year. The reason to do an one-year follow-up was our impression from earlier studies that MTBI patients at this time would have stabilized rather permanently [1, 14, 37]. Nevertheless, it has been argued that even longer follow up would be of interest [6, 11, 20].

Intervention increases awareness in patients which may affect the final outcome [24].

### *Relations to other studies*

There are very few controlled studies on the effects of intervention in reducing the prolonged effects of MTBI [9, 12]. The Cochrane Central Register of Controlled Trials [10] on MTBI yielded seven hits of which three [13, 36, 37] were relevant to the present study. In our study, the LiSat-11 revealed a statistically-significant

improvement for the intervention group for one item, ''physical health'', and a life satisfaction study conducted by Melin *et al.* [30] in a nationally representative Swedish population of subjects in their vocationally active years revealed that physical health and activity items play a significant role in the likelihood of being satisfied with life as whole [30]. In a sensitivity study by Paniak *et al.* [34] of three questionnaires where the SF-36 and CIQ were two of the instruments; the results revealed that the SF-36 was a sensitive instrument for measuring MTBI-related effects, but the CIQ was not sensitive enough, no differences were found between MTBI patients and normal controls [34]. In our study, the CIQ revealed no statistically significant differences between the groups. In our study, in the analyses of the intervention group and control group one year after injury, the SF-36 revealed that the whole MTBI group reported statistically-significantly poorer health-related quality of life than a Swedish reference group.

### *Limitations of the present study*

The recruitment to this study of individuals free of known previous clinically significant brain disorders and substance abuse, excludes about one third of the general population suffering from MTBI. Bearing in mind our urban–rural catchment area, our exclusion of 30 percent may be higher in a more urbanized region. We have no data on socio-economic status or financial compensation, also known to have strong influences on late sequelae after MTBI [5, 35]. Several authors emphasize the importance of very early intervention of MTBI patients in order to achieve positive results [41, 46, 52]. The reason is that early intervention may prevent that the regularly occurring symptoms during the first days and weeks from eliciting secondary long lasting symptoms.

In summary, our data and the results from similar studies [13, 36, 37, 51] call into question the recommendations forwarded that all MTBI patients would benefit from routine early intervention by a specialist service [46, 51, 52]. We agree with previous studies that all patients having sustained MTBI should, at discharge from hospital, get written information about MTBI how to handle the situation and what to do if they do not recover within a few months [31, 41, 43]. Patients who claim that they have been restored to previous health two to eight weeks (median) 3 weeks after MTBI will recover within a year, but patients who have several PCS two to eight weeks (median 3 weeks) after the MTBI run the risk to develop late sequelae.

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## Comments

This is a carefully conducted trial of early intervention after minor head injury. The overall technical quality of the trial is generally good, though a weakness is the retrospective estimates that were used. Lack of blinding of patients and therapists is an issue, but then it is difficult to see how this can be avoided in a trial of this type. Blinding on outcome assessment was achieved by using postal follow-up.

There are two main findings: first a substantial proportion of minor head injury patients still report problems one year post-injury, and second, in the current trial early intervention was not effective in reducing these problems.

The authors suggest that failure to find an effect of intervention may in part have arisen because of the stringent selection criteria used. One third of patients were excluded because of pre-existing problems, but these may be the cases that are particularly vulnerable to the effects of minor head injury and in whom benefits of intervention would be particularly apparent. It is also possible that other forms of intervention would be effective. While involving a range of specialities, the current trial primarily emphasised occupational therapy. The kinds of problems that people report after minor head injury often have a strong emotional component, and a more specifically psychological intervention might be helpful in some cases.

*Lindsay Wilson*
Stirling

This is an interesting paper which shows (in a randomized trial with one year of follow up) that post concussion symptoms were unaffected by a rehabilitation intervention.

The study is well constructed, the tests appropriate and the results reasonable.

*Gillian McHugh*
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