Postcards from the EDge: 24-month outcomes of a randomised controlled trial for hospital-treated self-poisoning

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Background Repetition of self-poisoning is common.

Aims To report the 24-month outcomes of a non-obligatory postcard intervention (plus treatment as usual) compared with treatment as usual.

Method In a randomised-controlled trial (Zelen design) conducted in Newcastle, Australia, eight postcards were sent to participants over a 12-month period. The principal outcomes were the proportion of participants with one or more repeat episodes of self-poisoning and the number of repeat episodes per person.

Results No significant reduction was observed in the proportion of people repeating self-poisoning in the intervention group (21.2%, 95% CI 17.0–25.3) compared with the control group (22.8%, 95% CI 18.7–27.0; χ² = 0.32, d.f. = 1, P = 0.57); the difference between groups was −1.7% (95% CI −7.5 to 4.2). There was a significant reduction in the rate of repetition, with an incidence risk ratio of 0.49 (95% CI 0.33–0.73).

Conclusions A postcard intervention maintained the halving of the rate of repetition of hospital-treated self-poisoning events over a 2-year period, although it did not significantly reduce the proportion of individuals who repeated self-poisoning.

Declaration of interest None.
This design is a variation on the standard randomised controlled experimental design, in which participants were randomised to control or intervention before consent was sought. In the single consent version, written informed consent to receive the intervention (eight non-obligatory postcards) was sought only from participants randomised to the intervention. The outcomes were assessed by an intention-to-treat analysis based on randomisation status.

The Hunter Area Health Research Ethics Committee approved this study, including the randomised consent design.

Randomisation
Randomisation was by database (HanDBase version 2.0; DDH Software, Wellington, Florida, USA) on a personal digital assistant (Palm III; Palm, Inc., Sunnyvale, California, USA) which was populated with a pre-generated randomisation schedule (in blocks of ten) and carried by the duty toxicologist. To avoid recruiting patients more than once, identification information was searched in this database before enrolment. To maintain masking to allocation status during recruitment, randomisation was not revealed until after all information was entered and eligibility determined. Randomisation status was then revealed in order to obtain patient consent. To monitor any potential alterations (interference) a duplicate record was kept in a hidden field of the database and a copy held on a separate computer for later verification of correct randomisation status.

All other clinical and research staff were unaware of allocation.

Intervention
A new intervention was developed based on the study by Jerome Motto, which demonstrated reduced death by suicide in a psychiatric hospital in-patient population (Motto, 1976; Motto & Bostrom, 2001). The new intervention was a series of eight ‘postcards’ sent in a sealed envelope in months 1, 2, 3, 4, 6, 8, 10 and 12 after discharge (the postcard is shown in the online supplement to this paper). All participants received treatment as usual.

Sample size
During study planning several sample sizes were calculated based on different estimates of possible effects for the 12-month outcomes (Carter et al., 1999). A difference in proportions (5% significance level, 80% power) of 15% to 10% required 1364 participants, 20% to 10% required 392 participants and 30% to 20% required 293 participants. On the basis of clinical experience and previous research it was anticipated that 15–30% of the control group would self-poison again within 12 months, with an average of two episodes, meaning overall self-poisoning rates of 30–60%. A sample of 400 per group would allow detection of absolute differences between groups of 10–15% (5% significance level, 80% power) and 12–17% (5% significance level, 90% power), yielding relative risks of 0.67–0.75 and 0.60–0.72 (80% and 90% power respectively). This sample size would be adequate to detect differences in the proportion of participants who had any episode of self-poisoning of 7–9% (80% power) and 8–10% (90% power and 5% significance level), which we considered would represent a clinically significant reduction.

Statistical analyses
Data were analysed using the computerised statistical packages SPSS version 10.0 and Intercooled Stata versions 7 and 8. The difference in proportions of participants with any readmission for self-poisoning was tested with χ² analyses. For the number of readmissions per individual, a negative binomial regression was undertaken to compare the risk of self-poisoning events per individual in the postcard group relative to the control group and is reported as incidence risk ratio (IRR) with 95% confidence intervals. Two subgroup analyses, using negative binomial models, were undertaken for the treatment effect for male and female groups, since a post hoc analysis of 12-month outcomes suggested a gender effect (Carter et al., 2005).

Intent to treat
We assessed 922 patients for eligibility, of whom 130 (16%) were ineligible (Fig. 1), leaving 772 potential participants (control
group n=394 intervention group n=378). Among the intervention group, 76 refused the intervention, 1 missed the intervention as planned and 32 did not receive the full intervention (this was due to these people being unavailable, their postcards being returned ‘not known at this address – return to sender’). Twenty people in the control group received the intervention owing to clerical errors, but were retained in the control group as data were analysed as intention to treat, based on randomisation.

RESULTS

The characteristics of the sample at baseline are summarised in Table 1. Previous episodes of hospital-treated self-poisoning were recorded for 17% of the total sample, (129/772), 17% of the control group (66/394) and 17% of the intervention group (63/378). The frequency of the poisoning subtypes were: pharmaceuticals only, 473 (61%); pharmaceuticals plus alcohol, 217 (28%); opioid or amphetamine, 20 (3%); carbon monoxide, 17 (2%); herbicide or rodenticide, 11 (1%); insulin, 7 (1%); self-poisoning with additional self-harm 23 (3%); and unknown poison, 4 (1%).

Proportion of sample repeating self-poisoning

In the intervention group 21.2% (80/378; 95% CI 17.0–25.3) had one or more readmissions for self-poisoning compared with 22.8% (90/394; 95% CI 18.7–27.0) in the control group 24 months after baseline, a non-significant difference (χ²=0.317, d.f.=1, P=0.57), the difference between groups being −1.7% (95% CI −7.5 to 4.2).

Number of repeat admissions

There were 310 cumulative readmissions in the control group and 145 in the intervention group (Fig. 2). Table 2 shows the relative risks for the intervention group compared with the control group from the negative binomial regressions. The risk of repetition was statistically significantly lower in the intervention group (IRR=0.49, 0.49, 95% CI 0.33–0.73). Separate subgroup analyses by gender showed the treatment was effective for women (IRR=0.49, 95% CI 0.30–0.80) but not for men (IRR=0.97, 95% CI 0.50–1.88. Readmissions by intervention group and gender are shown in Table 3.

Table 1  Characteristics of the study sample

<table>
<thead>
<tr>
<th></th>
<th>Missing data n</th>
<th>Total sample (n=772)</th>
<th>Control group (n=394)</th>
<th>Intervention group (n=378)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Categorical variables, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>1</td>
<td>524 (68)</td>
<td>291 (74)</td>
<td>233 (62)</td>
</tr>
<tr>
<td>Married¹</td>
<td>31</td>
<td>256 (35)</td>
<td>118 (31)</td>
<td>138 (38)</td>
</tr>
<tr>
<td>Employed</td>
<td>153</td>
<td>162 (26)</td>
<td>88 (27)</td>
<td>74 (26)</td>
</tr>
<tr>
<td>Admitted to intensive care</td>
<td>0</td>
<td>113 (15)</td>
<td>60 (15)</td>
<td>53 (14)</td>
</tr>
<tr>
<td>Admitted outside office hours</td>
<td>0</td>
<td>581 (75)</td>
<td>296 (75)</td>
<td>285 (75)</td>
</tr>
<tr>
<td>Discharged to psychiatric hospital</td>
<td>2</td>
<td>208 (27)</td>
<td>106 (27)</td>
<td>102 (27)</td>
</tr>
<tr>
<td>Previous admission for self-poisoning</td>
<td>0</td>
<td>129 (17)</td>
<td>66 (17)</td>
<td>63 (17)</td>
</tr>
<tr>
<td><strong>Continuous variables, median (Q1–Q3)²</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age, years</td>
<td>0</td>
<td>33 (24–44)</td>
<td>34 (23–45)</td>
<td>33 (24–42)</td>
</tr>
<tr>
<td>Length of stay, h</td>
<td>0</td>
<td>18 (12–30)</td>
<td>18 (13–31)</td>
<td>17 (12–29)</td>
</tr>
<tr>
<td>Number of prior self-poisoning admissions</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Number of psychiatric diagnoses</td>
<td>0</td>
<td>2 (1–3)</td>
<td>2 (1–3)</td>
<td>2 (1–3)</td>
</tr>
</tbody>
</table>

¹ Includes de facto relationships.
² First quartile–third quartile.

DISCUSSION

Strengths and weaknesses of the study

This study had several strengths. First, a randomised consent design was used, which was suited to this study and this clinical population. In this study the baseline characteristics and principal outcomes were tracked by the HATS database, allowing for complete follow-up. Second, the quality of the randomisation was strong, with randomisation undertaken using a handheld personal computer device in combination with another computer which could detect any errors of allocation status and interference with the randomisation. Third, all participants, clinicians and research staff were masked to the primary outcome measurement; only the recruiting toxicologists and the secretary responsible for managing the mailing database and postcards were aware of allocation status. Owing to the randomised design, the quality of masking to allocation and to outcome, and the service model of HATS in which all cases of self-poisoning are admitted to hospital, we believe that there are few threats to internal validity in this study.

There were some limitations to consider for this study and caution needs to be used when interpreting the results. Less than a quarter of the participants self-poisoned a second time, and a subgroup showed a highly skewed pattern of more than one repeat episode. It is not known to what extent the HATS referral population and model of clinical service (Whyte et al., 1997) would be generalisable to other settings. This study investigated patients who self-poisoned and the results cannot necessarily be generalised to patients with other forms of self-harm. We do not currently have data available on mortality and suicide outcomes for the study participants. A previous longitudinal study in our centre found a 1% suicide rate after 24 months and nearly 2% suicide rate after 5 years, which would translate to 8 suicide deaths and 16 suicide deaths respectively (Reith et al., 2004). These suicide rates are lower than the 12-month 1.8% rate reported in a recent meta-analysis of psychosocial interventions after self-harm (Crawford et al., 2007). We intend to be able to report the mortality and suicide outcomes for the 5-year follow-up of the Postcards from the EDge project in the future.

Fig. 2  Cumulative readmissions to hospital for treatment of self-poisoning (24 months; unadjusted for multiple admissions).
Replications of this study and additional effectiveness trials would be necessary before widespread implementation could be considered. The decision to include a subgroup analysis based on gender was a post hoc one based on the findings from the primary outcomes at 12 months. Caution should always be used in interpreting such subgroup analyses because of (unplanned) reduced sample sizes, and judgement needs to be exercised regarding the biological plausibility of such analyses. There may also have been a conservative estimate of treatment effect because 20 persons in the control group were inadvertently exposed to the intervention, whereas 76 persons in the treatment group did not consent to receive the intervention and a further 32 persons were not exposed to the intervention.

Implications of the study
The simple postcard intervention used in this study was previously shown to have nearly halved the number of readmissions for self-poisoning within 12 months: IRR=0.55, 95% CI (0.35-0.87) (Carter et al, 2005). This study of 24-month outcomes showed that this benefit was maintained for a further 12 months after the final contact by postcard: IRR=0.49, 95% CI 0.33-0.73. There were 422 bed-days used by the control group and 183 bed-days used by the postcard group, a total of 239 bed-days saved. This represented a considerable ongoing saving in opportunity costs, availability of hospital beds and decrease in emergency department workload. This low-cost intervention seems to have substantial cost-effectiveness. The simplicity of the intervention means that it could be delivered from hospitals that do not have extensive resources. The difference in total readmissions for self-poisoning came from one main source – women with three or more repeat admissions (see Table 3) – which accounted for a difference of 165 repeat admissions (210 in the control group and 45 in the intervention group).

### Table 3: Number of repetitions of self-poisoning by gender and experimental group

<table>
<thead>
<tr>
<th>Number of repetitions</th>
<th>Control group (n=394)</th>
<th>Intervention group (n=378)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Men (n=102)</td>
<td>Women (n=291)</td>
</tr>
<tr>
<td></td>
<td>n (%)</td>
<td>Total repetitions</td>
</tr>
<tr>
<td>None</td>
<td>83 (81)</td>
<td>0</td>
</tr>
<tr>
<td>One</td>
<td>14 (14)</td>
<td>14</td>
</tr>
<tr>
<td>Two</td>
<td>3 (3)</td>
<td>6</td>
</tr>
<tr>
<td>Three or more</td>
<td>2 (2)</td>
<td>9</td>
</tr>
</tbody>
</table>

1. One control group participant with missing data for gender had 13 readmissions.
with borderline personality disorder (Bateman & Fonagy, 2001; Linehan et al., 2006) or a group of only 119 participants from an initial sample of 587 patients presenting with self-poisoning (Guthrie et al., 2001), which makes comparison with our study more difficult. However, these four studies taken together suggest that if some impact on reduction of repetition of self-harm or self-poisoning behaviour can be made, then perhaps the effects might be sustained over a period beyond that of the intervention.

Although it may also be inferred that some participants in our study learned sustained alternative behaviours to self-poisoning, there was no particular component of the intervention that aimed to induce these specific behavioural changes. The mechanism for the long-term benefits in the Postcards from the EDge study remains speculative. We have planned a qualitative study to explore the question of what mechanisms might have contributed to this. We also do not know whether there was any change in the pattern of psychiatric hospital, psychiatric community service or primary care service use that might have been a mediating factor in the difference in repetition events, but we hope to be able to explore some of these possibilities in the planned 5-year follow-up study.

Comparison with other brief interventions

There are other brief interventions for repetition of hospital-treated self-harm or self-poisoning that can be considered. One of the best-known low-cost interventions for self-harm in the UK was the green card study and the subsequent crisis telephone card study, which showed no difference in the proportion of those repeating self-harm at 6 months (Evans et al., 1999) or at 12 months (Morgan et al., 1993; Evans et al., 2005). The first of these studies (n=212) was underpowered and included only those presenting for the first time with self-harm, who subsequently showed a repeat rate of self-harm of only 8% (Morgan et al., 1993). The second variation (n=827) was adequately powered, used a self-harm case register to define repetition, and found no difference in proportions of those repeating self-harm, with a 12-month repetition rate of 20% (Evans et al., 2005). In France, a telephone contact intervention delivered either 1 month or 3 months after an episode of self-poisoning showed no difference in the proportion of a combined ‘adverse effects’ outcome or proportion of self-reported suicide attempt (Vaiva et al., 2006). That study (n=605) was adequately powered, used a stratified (based on more than four suicide attempts in 3 years), three-arm design and had a 12-month repeated attempt suicide rate of 17%. A multicentre UK study used a manual-assisted cognitive–behavioural therapy intervention for established cases of repeated self-harm and showed no difference in proportion of those with self-reported repeat parasuicide (Tyrer et al., 2003). This study (n=480) was adequately powered (for an expected repetition rate of 45%), used a stratified (based on parasuicide score) design and had a 12-month parasuicide rate of 43%. The comparison condition for these studies was standard treatment or treatment as usual and for the Postcards from the EDge study it was postcards plus treatment as usual v. usual treatment alone. Each of these studies showed a similar non-significant reduction in the proportion of those repeating self-harm (patient rate) of 2.2–7.0% (Crawford & Kumar, 2007). However, none of these studies of brief, low-cost interventions analysed the number of episodes of repeated self-harm (event rates) as an outcome, and most used different definitions of the primary outcome and different methods of estimating the rates of that outcome, so comparison with the beneficial finding from the Postcards from the EDge study is difficult despite the similarities of intent underlying the interventions.

Concluding remarks

This study of hospital-treated self-poisoning showed that a low-cost postcard intervention was effective in reducing the number of events per individual by a relatively reduction of more than 50%, which was clinically and statistically significant. The postcard intervention continued to be effective in reducing repeat episodes of hospital-treated self-poisoning for 1 year after the intervention ceased.

ACKNOWLEDGEMENTS

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REFERENCES


discharged from an emergency department: randomised controlled study. BMJ. 332, 1241–1245.


The postcard used in the intervention

Hunter Area
Toxicology Service

Dear «FirstName»

It has been a short time since you were here at the Newcastle Mater Hospital, and we hope things are going well for you.

If you wish to drop us a note we would be happy to hear from you.

Best wishes,

Dr Andrew Dawson

Dr Ian Whyte

Newcastle Mater Matericordiae Hospital
Locked Bag 7, Hunter Regional Mail Centre NSW 2310
Phone: 49 211 283 Fax: 49 211 670
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Supplementary Material
Supplementary material can be found at:
http://bjp.rcpsych.org/content/suppl/2007/12/03/191.6.548.DC1

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