UNPLANNED REPRESENTATION TO HOSPITAL BY PATIENTS WITH DIABETES: DEVELOPMENT AND PILOT FEASIBILITY TESTING OF A SCREENING TOOL

RUNNING TITLE

Unplanned representations with diabetes

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PROVENANCE

The study was conceived as an initiative of South East Sydney Local Health District. LP, JG and WV conceived and designed the study proposal, and secured funding. JG supervised data collection. LP and SJ analysed the data. All authors prepared and approved the manuscript.

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HUMAN RESEARCH ETHICS APPROVAL

The study was approved by South Eastern Sydney Local Health District Human Research Ethics Committee (approval number: 16/211 (LNR 16/POWH/421).

KEYWORDS

Diabetes Mellitus; Emergency Department; Hospital; Cognitive; Feasibility; Nurses; Representation; Screening.

GEOLOCATION

This study was undertaken in Randwick (Sydney), New South Wales, Australia.

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ABSTRACT

Background

Unplanned representation of patients with diabetes recently discharged from emergency department or in-patient hospitals is a common but complex problem worldwide. This study set out to examine the feasibility of a risk screening interview and whether component characteristics may be associated with unplanned representation of patients with diabetes to a tertiary metropolitan hospital.

Methods

A screening interview comprised of demographic, social and clinical characteristics was developed and piloted using prospective cross-sectional survey design. A convenience sample of 55 patients was recruited and screened. Outcomes were the occurrence of unplanned representation to hospital within 28 or 90 days of hospital discharge from the index presentation.

Results

The screening interview was shown to be broadly feasible and acceptable for use by staff and patients, with identified areas for modification. Seventeen participants (30.9%) experienced unplanned representation within 90 days of hospital discharge; for 13 participants (23.6%) this occurred within 28 days. Characteristics linked with unplanned representation to hospital were identified.

Conclusions

Preliminary data indicated the feasibility of tool use and informed refinement for future testing of the ability of the screening interview to predict those patients with diabetes at high risk of unplanned representation to hospital to enhance effective care planning.

IMPACT STATEMENT

Patients with diabetes commonly present to Emergency Departments, and demonstration of the feasibility of a screening interview to determine those at elevated risk of unplanned representation is an important step towards effective management. Data supported refinement and future testing of the new screening interview.

INTRODUCTION

Rising rates of unscheduled representations of patients recently discharged from Emergency Department (ED) or in-patient hospital settings are presenting major challenges worldwide. Associated with ED overcrowding, increased hospital admissions and adverse events, and impacting the provision, quality and cost of acute care [1,2], unplanned representation rates commonly serve as indicators for health service monitoring and evaluation. However, around one-third of representations to ED settings have been identified as potentially avoidable[3-5], and studies have explored the predictive power of various characteristics. From a health systems perspective, misdiagnosis, premature or inappropriate discharge have been flagged[5-7]; from the patients' perspective, reasons include uncertainty about their clinical condition, insufficient follow-up instructions, inadequate or inconvenient access to subsequent care, and social circumstances[3,5-7]. Diabetes has been flagged as a risk factor within generic models of unplanned representation risk[8,9], but few studies have reported rates of representation to hospital specifically of patients with diabetes recently discharged from ED or in-patient hospital care[10,11]. This is of special importance considering the increasing rates of diabetes world-wide[12]. Determination of the frequency of representation amongst patients with diabetes and demonstration of related characteristics may help identify areas for improvement in healthcare to reduce avoidable unplanned representation.

This study was therefore established to examine, in patients with diabetes:

- The feasibility of screening with a composite interview for common characteristics, identified in the literature and in local audit data of patients with unplanned representations (i.e. comorbidities, polypharmacy, having an

identified carer, or issues with mental health, cognition or substance use[7,13]); and

- Whether these characteristics were linked to subsequent unplanned representation to hospital within 28 or 90 days after discharge from the index presentation.

METHODS

Design and data collection

This pilot study employed a prospective cross-sectional observational survey design. A screening interview was constructed. Target variables were addressed with established tools, combined with questions seeking socio-demographic data assembled into a short clinical interview format. This was discussed and reviewed by an external group of clinicians. The final format organised data collection into different sections. The first sought demographic information from the patient concerning their education and schooling, social circumstances and whether they received any form of help, formal or informal, with activities of daily living (ADL). A second section collated participants' demographic, social and clinical data from the patients' healthcare record, including recorded diagnoses and medications, to determine the feasibility of using routinely available data. Finally, participants undertook three assessments, chosen to test a broad range of cognitive skills. The specific measures were selected considering their use with patients presenting to hospital; assessments needed to be valid and reliable, relatively brief and quick to complete, simple to administer, score and interpret.

The Clock Drawing Test

Originally used to assess visuo-constructive abilities, the Clock Drawing Test (CDT) screens a wide range of cognitive skills including semantics, planning, visual-spatial abilities, visual memory, motor planning, abstraction and response inhibition[14,15]. Studies have shown the CDT has good validity and reliability in various disease and age populations, although its use in detecting early and mild cases of dementia is limited[16-18].

The CDT was adopted in the form advocated by Freedman et al[19] with the command condition of Hubbard et al[20], where the patient hand-draws the circle. Participants were instructed to "draw a face of a clock, put all the numbers in where they should go and set the hands to ten past eleven". If the participant drew clock hands of equal length the participant was prompted to "show me which hand is the minute hand and which is the hour hand". With no accepted consensus for scoring, criteria used in the Montreal Cognitive Assessment[21] were adapted by two neuropsychologists, providing a maximum score of 8 (contour integrity maximum score 1, numbers maximum score 3, and hands maximum score 4); a score <8 was deemed a failed test.

The Working Memory Test

The Frontier Executive Screening tool was originally designed to measure components of cognitive function and differentiate between behavioural variants of dementia[22]. The Working Memory Test (WMT) subsection of this tool evaluates short-term memory and comprises two practice and seven test items of letter sequences ranging from two to five letters, testing recall of verbally presented letter strings of increasing length. Participants repeat letter sequences in reverse order; for each difficulty level one point is awarded, with a bonus point if all tests are completed successfully, yielding scores

between 0 and 5 where higher scores indicate better recall. The WMT has been shown to have acceptable validity and reliability[23].

The Color Trails Test

The Color Trails Test (CTT) is a language-free version of the Trail Making Test[24,25], designed to evaluate visual attention and frontal systems functioning[26,27]. Use does not require English language skills. Studies have shown the CTT has good validity and reliability in varying disease and geographical populations[28,29].

Participants were asked to draw a line connecting circles numbered 1-25 in sequence. They were then asked to draw a line between numbered circles, maintaining the number sequence but alternating between pink and yellow colours (numbers are presented twice, in pink and yellow, so the distracter item should be ignored). Aspects such as the occurrence of errors, need for prompting near misses and time required to complete each part of the CTT were documented.

Sample

A convenience sample was recruited of patients who presented to the ED of a tertiary metropolitan hospital in New South Wales, Australia. To be eligible, participants required a diagnosis of any form of diabetes except gestational diabetes (due to its transient nature); to be deemed medically stable (i.e. with no vital signs outside medically agreed normal ranges); able and willing to give informed consent, including through use of interpretation services if required. Diabetes-related health problems were not required to be the primary cause of hospital presentation.

As a pilot feasibility study, a sample size of around 50 participants was anticipated. Potentially eligible patients were identified via electronic medical records of

presentations to the ED and admission lists for the hospital, cross-checked with the meal type ordered for the patient. The research assistant (a psychologist) confirmed the diagnosis of diabetes and the patients' medical stability with attending clinicians prior to recruitment.

Data collection procedures

The study was approved by South Eastern Sydney Local Health District Human Research Ethics Committee (approval number: 16/211 (LNR 16/POWH/421). Data were collected over three weeks in November-December 2016.

Participants were recruited in the hospital ED and wards. Potential participants were introduced to the research assistant by a clinician. The research assistant provided written and verbal information about the study. With written informed consent, the screening interview including the three cognitive assessment measures was administered at the bedside. Where possible, participants were seated on chairs or a bed, completing paper-based cognitive tests on a clipboard or a table. All testing was conducted in adequate lighting with participants using their glasses and/or hearing aids, if required. Where discrepancies occurred between the demographic and health data obtained from participants and their health records, items were reviewed by research team members.

Each participant's electronic medical record was accessed after their hospital discharge to determine any repeat presentations recorded as occurring within the subsequent 28 or 90 days: measures used by New South Wales Health for health system performance reporting[30]. Where a repeat presentation had occurred, related details were extracted.

Data analyses

Data were entered into SPSS© version 24 software for analysis. Cognitive scores were considered as ordinal scores (where appropriate) and dichotomised. The CDT and WMT scores were collapsed to all components correct or with any error (score 8 or <8, and 5 or <5, respectively). CTT scores were categorised as consistent with or as outside normative time ranges for age and education[31].

All medications prescribed at hospital discharge were counted and coded as polypharmacy where three and more medications were prescribed in addition to those for diabetes, operationalised as a total of five or more regular prescriptions[32]. Other medical conditions (co-morbidities) and any outpatient or community health follow-up appointment attendance were dichotomised as present/absent. Participants' reports of comorbidities besides diabetes, history of mental illness, developmental delay, dementia, current substance use (excluding tobacco/nicotine) and formal/informal carer were coded as present/absent.

Feasibility testing entailed process, resource and management assessment [33]. Process assessment considered numbers of eligible members of the targeted population and recruitment rates, data collection assessments and the proportion of complete datasets collected. Resource assessment considered departmental willingness, motivation and capacity to be involved in the study, and time taken to conduct each stage of the study protocol. Management assessment considered the matching of participants' data from different sources, and accuracy of data entry[33]. This paper reports data derived from the screening interview only.

Descriptive statistics were calculated to describe the sample and in relation to representation and/or hospital admission within 28 and 90 days following the index presentation. Associations were sought between groups who did and did not have an unplanned representation, and demographic and clinical variables including age, co-

morbidity, polypharmacy, mental illness or substance use, CDT, CTT and WMT scores. P values <0.05 were considered significant.

RESULTS

Feasibility testing

Feasibility was tested in relation to processes, resources and management[33]. Process assessment revealed that a daily average of 40% of participants (n=2) who were approached were recruited and screened. Of those not recruited, half (n=40) were missed due to practical issues such as absence from clinical areas; one quarter (n=21) were deemed too unwell to participate; one quarter (n=20) declined.

Considering completion of the cognitive assessments, the CDT and WMT both appeared broadly feasible to use and well accepted by patients. One blind participant did not undertake the CDT; all 54 others were able to complete it. Three (5.5%) participants did not undertake the WMT due to neurological impairment; all 52 participants that undertook this test were able to complete it. The CTT performed less well. Six (10.9%) of the 55 participants that undertook the first component of the CTT did not complete it, finding it complicated and difficult, too tiring or impacted by their comorbidities. Six participants took >200 seconds for this component; the median (25, 75 quartile) completion time was 78 (45,143.5) seconds. Twelve of the 39 (30.8%) participants who completed the second component took >200 seconds; the median completion time was 139 (99, 213) seconds. In total, 10 (18.2%) participants did not complete both components of the CTT.

Resource assessment findings revealed that all wards and departments demonstrated willingness, motivation and capacity to be involved in the study. Mean ±SD total screening interview duration was 18 minutes 14 seconds ± 5 minutes 40 seconds.

Comparison of variables such as co-morbidities, prescribed medications and presence of a carer sourced both from patient report and routine data extraction, did not reveal discrepancies. A 20% audit of accuracy of computer data entry found no errors.

Participants' Characteristics

A total of 55 participants were recruited, the majority of whom (n=39, 70.9%) completed the screening tests after being admitted to hospital. One Greek, one Indonesian and one Malaysian participant required interpretation. Two participants (3.6%) died during the study period; their data were retained in analyses. Participants' ages ranged from 20-90 years with mean ± SD 67.5 ± 15.2 years; over half were male (n=29, 52.7%) and had attended school in Australia (n=32, 69.6%) (Table 1). Participants predominantly had type 2 diabetes (n=42, 85.7% vs type 1 diabetes n=6, 12.3% vs other n=1, 2%) and other comorbidities (n=51, 92.7%), with a median (25, 75 quartile) 6 (4, 8) diagnoses. Most (n=48, 87.3%) participants were prescribed medications in addition to those for diabetes; of 44 participants who advised the number of additional medications prescribed, almost all (n=40, 90.9%) were classified as polypharmacy. Excluding three participants prescribed >20 medications, participants were prescribed a median 10 (7.5, 14) other medications. Almost half the participants lived alone (n=22, 40%), had an identified carer (n=24, 43.6%) and received some form of assistance with ADL (n=23, 41.8%). Around one quarter (n=13, 23.6%) self-reported experiencing emotional distress. One in five (n=10, 21.3%) had a history of mental illness, around one in 14 (n=4, 8.5%) of dementia and one patient (2.1%) had developmental delay (Table 1). No participants reported substance use.

Planned outpatient department attendance following the index hospital presentation was uncommon. Overall, nine (16.4%) participants had an initial planned attendance

within 90 days following the index presentation/discharge, for six (10.9%) this occurred within 28 days. The median (25, 75 quartile) length of time between hospital discharge from the index presentation and first planned attendance was 22 (2.5, 70) days.

Clock Drawing Test Findings

Of 54 participants who undertook the CDT, 17 (31.5%) obtained the maximum score of eight (Table 2); the mean ±SD score was 6 ±2.2. Almost all participants completed the contour component accurately (n=52, 96.3%) but almost half made errors in the clock numbering (n=24, 44.4%) and in drawing the clock hands (n=31, 57.4%). The maximum score occurred significantly more often amongst younger participants (60.4±18 vs 70.3±12.8 years, df=52, t=2.320, p=0.024). There were non-significant trends to greater likelihood of maximum score in female participants (n=9, 16.7% vs n=8, 14.8%), in those with comorbidities (n=14, 25.9% vs n=3, 5.6%), polypharmacy on discharge (n=10, 20% vs n=4, 8%), who did not identify a carer (n=12, 22.2% vs n=5, 9.3%), had no history of mental illness (n=11, 23.9% vs n=3, 6.5%), lived alone (n=9, 16.7% vs n=8, 14.8%), and who did not require help with ADL (n=12, 22.2% vs n=5, 9.3%).

Working Memory Test Findings

Of 52 participants who undertook the WMT, four (7.7%) obtained the maximum score of five (Table 2); the mean ±SD score was 2.4±1. The maximum score occurred significantly more frequently amongst younger participants (52.3±10.8 vs 67.7±14.8 years, df=50, t=2.307, p=0.047), with non-significant trends to greater likelihood amongst participants with comorbidities (n=3, 5.8% vs n=1, 1.9%).

Color Trails Test Findings

Around half of the 49 participants who completed the first component of the CTT (n=26, 53.1%), and two-thirds (n=29, 64.4%) of the 45 participants who completed the second component, did so without error and scored within normative reference time ranges (Table 2); 23 (51.1%) participants completed both components without error and scored within normative reference ranges. Both CTT components were significantly more likely to have been completed without error and within normative reference time ranges where participants did not have an identified carer (n=20, 44.4% vs n=3, 6.7%, Fishers exact test p=0.011), or require help with ADL (n=21, 46.7% vs n=2, 4.4%, Fishers exact test p=0.003). Non-significant trends indicated participants who completed both components of the CTT without error and within normative reference time ranges were more likely to be female (n=12, 26.7% vs n=11, 24.4%), have a history of mental illness (n=14, 37.8% vs n=3, 8.1%), or live with someone (n=12, 52.2% vs n=11, 47.8%).

Unplanned Representation to Hospital

Unplanned hospital representations following the index event were common. Overall, 17 (30.9%) participants had at least one unplanned representation within 90 days from the index presentation, for 13 (23.6%) this occurred within 28 days of hospital discharge. The median (25, 75 quartile) duration between hospital discharge from index presentation and first unplanned representation was 12.3 (2.5, 27.5) days. Following this initial unplanned representation, 12 (70.6%) participants were discharged home from the ED, three (17.7%) were admitted to ward settings and two (11.8%) represented to another hospital. Eight (14.6%) participants had more than one unplanned

representation within 90 days following the index presentation, and three (5.5%) participants had three unplanned representations.

The profiles of respondents with and without unplanned representation during the 90 days following hospital discharge from the index presentation were not significantly different, although different trends were observed. Participants who experienced at least one unplanned representation during the 90 days following hospital discharge tended to be older (mean ±SD 73.4±13.9 vs 64.9±15.1 years), more often female (n=10, 18.2% vs n=7, 12.7%), have an identified carer (n=10, 18.2% vs n=7, 12.7%), and no history of mental illness (n=14, 29.8% vs n=3, 6.4%) or dementia (n=14, 29.8% vs n=3, 6.4%). Those who experienced unplanned representation were also less likely to live alone (n=12, 21.8% vs n=5, 9.1%), and more likely to require help with ADL (n=10, 18.2% vs n=7, 12.7%).

Although not statistically significant, participants with maximal CDT scores were less likely to experience unplanned representation within 28 (n=9, 16.7% vs n=4, 7.4%) or 90 days (n=11, 20.4% vs n=5, 9.3%) following discharge from the index presentation. Similarly, participants with maximal WMT scores were less likely to experience unplanned representation within 28 or 90 days (both n=3, 5.8% vs n=1, 1.9%) following discharge from the index presentation. Non-significant trends indicated participants who completed both components of the CTT without error and within normative reference time ranges were less likely to experience unplanned representation within 28 days (n=4, 8.9% vs n=5, 11.1%), but more likely within 90 days (n=6, 13.3% vs n=5, 11.1%) following hospital discharge from the index presentation.

DISCUSSION

In Australia and elsewhere, rising rates of ED presentations are challenging staff's ability to provide appropriately timely care for all[5,34]. Nurses, the majority workforce, experience particular pressures. One in five ED presentations are of people aged ≥65 years[35], comprising co-morbid and complex presentations: a significant component of throughput. However, around one-third of representations to ED settings have been identified as potentially avoidable[3-5], and ways to decrease these unplanned representations are urgently required. The ability to determine those at high risk of unplanned representation might offer the opportunity for timely preventive care.

This study first examined the feasibility of using a screening interview to identify patients with diabetes at high risk of unplanned representation to hospital. Feasibility testing in relation to process, resource and management revealed unsatisfactory features in the CTT component. Participants found this burdensome, and it was resource intensive in the time taken for completion, and difficult to score. This assessment was included on the basis that, as it did not require English language skills, it might have utility for assessing patients from non-English speaking backgrounds. However, findings indicated the instrument was unsuitable for this clinical population in a busy clinical setting. Overall, management assessments, rates of completion and time taken to complete screening (with removal of the CTT) were satisfactory, and the screening interview appeared acceptable for patients and workable for staff.

The study then sought to identify whether the characteristics examined by the screening interview were linked to subsequent unplanned representation to hospital after the index presentation although, as a pilot, the study was not powered to determine significance. Averaging 67.5 years, participants were predominantly older, as are a major proportion of Australian hospital attendees [36], reflecting Australian population trends where, in

2017, more than one in seven were aged 65 years and over [36]. The influence of age may have been reflected in the CDT and WMT scores; few participants obtained maximum scores for either and those who did were significantly younger. Most participants had comorbid diagnoses, and these may also have necessitated healthcare use, consistent with Australian data highlighting the high burden of disease in older Australians [35].

Findings add to the body of evidence that highlights the frequency of unplanned representation, with almost one third (30.9%) of participants representing within 90 days of hospital discharge, almost one quarter (23.6%) within 28 days. Further, almost one in seven (14.6%) experienced more than one unplanned representation within 90 days. Conversely, planned follow-up within this period was much less frequent: only nine (16.4%) participants had a planned attendance during this time. Collectively, findings have implications for health outcomes and healthcare resources.

A number of characteristics including polypharmacy, living alone, having a carer, requiring help with ADL, mental illness, emotional distress and cognitive impairment have been identified in audits and studies of patients experiencing unplanned representation to hospital[7,13]. These characteristics were common amongst these patients. Statistical significance was not anticipated in this pilot feasibility study, but trends linked many of these characteristics in these patients with unplanned representation to hospital.

This was a feasibility study and its limitations should be considered in this light. Data were collected from only one site, during a relatively short period of time; seasonal variations may have affected patterns of presentation. We screened patients and timed assessments to minimise any potential effects of acute illness for cognitive function but cannot rule out this possibility. Data were not collected about access to community services. A systematic review of chronic disease patients found 90% of studies

identified geographic variation, with primary care quality and secondary care access frequent drivers of hospital admission rate variation [37]. With low rates of planned hospital follow-up, this may have been a consideration for unplanned representations at this hospital but this was not addressed in this study.

However, the impact of this work lies in its potential for the future. Patients with diabetes commonly present and make unplanned return visits to EDs. If patients at high risk of unplanned representation could be identified prior to discharge, tailored discharge plans including referrals to community services for patients discharged directly from the ED, might reduce or eliminate the need for future attendance. Nurses are key personnel in the support of patients within ED or inpatient settings, and are central to any screening interventions, to identification of ongoing care needs and planning for continuing care. With suitable preparation, the introduction of such an intervention might offer opportunities to broaden the nursing scope of practice as well as improve care quality and patient outcomes. .

CONCLUSION

This study successfully concluded the essential first steps towards development and testing of a screening interview to identify those patients with diabetes at elevated risk of unplanned representation after attending an ED. This study achieved its primary aim and this important first step of determining the feasibility of a screening interview that was acceptable to patients with diabetes, and to ED staff, and providing data to support future refinement and testing. Further study of the screening interview is justified.

CONFLICTS OF INTEREST

None.

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Table 1: Participant characteristics and unscheduled representation within 28 and 90 days of index hospital presentation/discharge

	All	Unscheduled representation			
		0-28 days		0-90 days	
	(n=55)*	No (n=42)	Yes (n=13)	No (n=38)	Yes (n=17)
Male	29 (52.7)	24 (43.6)	5 (9.1)	22 (40)	7 (12.7)
Type 2 diabetes (n=49)	42 (85.7)	30 (61.2)	12 (24.5)	28 (57.1)	14 (28.6)
Comorbid disease besides diabetes	51 (92.7)	38 (69.1)	13 (23.6)	34 (61.8)	17 (30.9)
Polypharmacy (n=51)	40 (90.9)	28 (63.6)	12 (27.3)	24 (54.5)	16 (36.4)
Identified carer	24 (43.6)	15 (27.3)	9 (16.4)	14 (25.5)	10 (18.2)
Mental illness (n=47)	10 (21.3)	7 (14.9)	3 (6.4)	7 (14.9)	3 (6.4)
Dementia (n=47)	4 (8.6)	2 (4.3)	2 (4.3)	1 (2.2)	3 (6.4)
Developmental delay (n=47)	1 (2.1)	0 (0)	1 (2.1)	0 (0)	1 (2.1)

**Unless stated. Number (%).*

Table 2: Cognitive assessment test scores, in relation to unplanned representation to hospital

	All	Unscheduled representation			
		0-28 days		0-90 days	
	n (%)	No n (%)	Yes n (%)	No n (%)	Yes n (%)
Clock Drawing Test (n=54)					
Contour error	2 (3.7)	2 (3.7)	0 (0)	1 (1.9)	1 (1.9)
Numbering error	24 (44.4)	18 (33.3)	6 (11.1)	16 (29.6)	8 (14.8)
Hands error	31 (57.4)	24 (44.4)	7 (13)	23 (42.6)	8 (14.8)
Any error: score <8	37 (68.5)	28 (51.9)	9 (16.7)	26 (48.1)	11 (20.4)
Working Memory Test (n=52)					
Error in 2 letters	2 (3.8)	2 (3.8)	0 (0)	1 (1.9)	1 (1.9)
Error in 3 letters	6 (11.5)	5 (9.6)	1 (1.9)	4 (7.7)	2 (3.8)
Error in 4 letters	31 (59.6)	25 (48.1)	6 (11.5)	22 (42.3)	9 (17.3)
Error in 5 letters	47 (90.4)	36 (69.2)	11 (21.2)	33 (63.5)	14 (26.9)
Any error: score <5	48 (92.3)	37 (71.2)	11 (21.2)	33 (63.5)	15 (28.8)
Color Trails Test					
Error or outside normative range in section 1 (n=49)	23 (46.9)	16 (32.7)	7 (14.3)	16 (32.7)	7 (14.3)
Error or outside normative range in section 2 (n=45)	16 (35.6)	13 (28.9)	3 (6.7)	13 (28.9)	3 (6.7)
Error or outside normative ranges: sections 1 or 2 (n=45)	22 (48.9)	17 (37.8)	5 (11.1)	17 (37.8)	5 (11.1)

n=Number.

STROBE Statement—Checklist of items that should be included in reports of ***cross-sectional studies***

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	Abstract
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	Abstract
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	1-3
Objectives	3	State specific objectives, including any prespecified hypotheses	3
Methods			
Study design	4	Present key elements of study design early in the paper	3
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	6
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	3-5
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*3-5*
Bias	9	Describe any efforts to address potential sources of bias	-
Study size	10	Explain how the study size was arrived at	6
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	7
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	7
		(*b*) Describe any methods used to examine subgroups and interactions	7
		(*c*) Explain how missing data were addressed	-
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	7
		(*e*) Describe any sensitivity analyses	-
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	8-10
		(b) Give reasons for non-participation at each stage	8
		(c) Consider use of a flow diagram	-
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	9-10
		(b) Indicate number of participants with missing data for each variable of interest	9-13
Outcome data	15*	Report numbers of outcome events or summary measures	8-13

Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	8-13
		(*b*) Report category boundaries when continuous variables were categorized	8-13
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	-
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	8-13
Discussion			
Key results	18	Summarise key results with reference to study objectives	13
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	15
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	13-14
Generalisability	21	Discuss the generalisability (external validity) of the study results	15
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Title page

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.