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Cohort profiles of the cross-sectional and prospective participant groups in the second Diabetes MILES - Australia (MILES-2) study

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ABSTRACT

Purpose: More research into the psychosocial aspects of diabetes is needed so that the health and quality of life of people with the condition can be improved. To fill this gap, we conducted the second Diabetes MILES – Australia study (MILES-2); a survey focused on psychological, behavioural and social aspects of diabetes. The aim of the MILES-2 study was to provide a) longitudinal follow-up of the original MILES 2011 study cohort; b) cross-sectional assessment of a new cohort.

Participants: Eligible participants were English-speaking Australians with type 1 or type 2 diabetes, aged 18-75. Longitudinal cohort participants were mailed / emailed study invitations directly by researchers. Random sampling (stratified by diabetes type, insulin use, state) of the National Diabetes Services Scheme (NDSS) database and nationwide advertisements were used to recruit new cohort participants. The final sample included N=2,342 eligible respondents (longitudinal cohort: n=504; 2015 new cohort: n=1,838); 54% had type 2 diabetes.

Findings to date: Survey respondents were from an advantaged socioeconomic background compared to the general population. Respondents with type 1 diabetes were over-represented in the new cohort (45%) relative to the planned stratification (40% type 1 diabetes, 60% type 2 diabetes). Respondents with insulin-treated type 2 diabetes were under-represented in the new cohort relative to the stratified sampling (42% invited versus 50% response). Participants who completed both the 2011 and 2015 surveys were more likely than those completing the 2011 survey only to have type 1 diabetes, report a higher education and annual income, and live in metropolitan areas. Participant feedback indicated the survey was perceived as relevant and valuable.

Future plans: The depth and breadth of the data available in this large sample will highlight unmet needs and priority areas for future investigation, and crucially, will inform policy, program and intervention development and evaluation in Australia.

Registration: Not applicable.

STRENGTHS AND LIMITATIONS

Strengths

- Key strengths of MILES-2 are the breadth and depth of quantitative data and the large, population-based sample size that affords the statistical power to investigate sub-groups and conduct multivariate analyses.
- The online survey methods were successful in generating a sample with gender balance, a wide age range, diverse socio-economic backgrounds, and a representative mix of people living in metropolitan, regional, and rural areas in all states and territories of Australia.
- The significance of the emerging longitudinal dataset is particularly noteworthy. For the first time, it will be possible to explore predictors and consequences of psychological distress and sub-optimal behavioural diabetes management in a non-clinical, population-based sample.

Limitations

- The response rates for both the longitudinal (26%) and the new cohorts (8%) in the MILES-2 survey were low.
- In the longitudinal cohort, substantial attrition was evident between the 2011 and 2015 surveys.
- Over- and under-sampling of certain groups were evident in the new cohort, as compared to the stratified sampling methods.
- Participants were from a relatively advantaged background, which may result in the under-estimation of social and emotional problems, and problems of healthcare access.

INTRODUCTION

Diabetes is one of the most challenging public health issues faced today. The number of people with diabetes has doubled globally in recent decades[1], and it is predicted that by 2040, 642 million people will have diabetes[2]. Australia is no exception to the global trend, where diabetes is the fastest growing chronic condition, and type 2 diabetes expected to be the largest health burden by 2023[3]. While the majority of Australians with diabetes have type 2 diabetes, the prevalence of both type 1 and type 2 diabetes is increasing[4].

There have been many developments in recent years to improve the management of diabetes: medications (e.g. insulin analogs, GLP-1 agonists, and sodium-glucose co-transporter 2 (SGLT2) inhibitors), technologies (e.g. wearable glucose monitoring devices, 'artificial pancreas', smartphone apps to support self-management), education (e.g. structured group training programs, online self-directed interventions) and healthcare access (e.g. multidisciplinary single-site care, subsidies for devices and consumables). Despite this, many people with diabetes still experience the condition as burdensome and unrelenting[5]. Achieving recommended treatment targets remains a significant challenge for many people with diabetes. Data from the National Health and Nutrition Examination Surveys (NHANES) in the USA indicate that less than 20% of people with diabetes have in-target HbA1c, blood pressure and cholesterol[6], and that this proportion of people meeting the recommended treatment goals has improved only slightly over time[7]. Australian data from 2013-2014 indicate that less than 50% of people with diabetes in primary care are meeting glycaemic targets, and only 20% are meeting all glycaemic and cardiovascular outcome targets[8]. In addition, severe hypoglycaemia remains all too common, with around 20% of adults with diabetes reporting severe hypoglycaemia in the past 3-6 months[9-11]. Systematic reviews demonstrate that psychological problems are prevalent[12-16], including clinically significant depressive symptoms (reported by 8-29% of adults with diabetes; though concerns about over-diagnosis have been raised[17])[12, 13, 18, 19], anxiety (among 7-14%) [14, 19, 20] and diabetes distress (among 18-39%)[19, 21, 22].

Impaired psychological well-being is not only associated with poorer quality of life, but also with less optimal self-care behaviours, hyperglycaemia, a higher risk of developing micro- and macrovascular complications of diabetes, and higher mortality rates[23-26]. This suggests that more research into the behavioural and psychological aspects of diabetes is needed to generate further insights into how both health and quality of life outcomes can be improved. Indeed, there have recently been calls for the prioritisation of research that seeks to understand and address the psychological well-being of people with diabetes[27, 28].

In 2011, we conducted the Diabetes MILES (Management and Impact for Long-term Empowerment and Success) – Australia study[29]. The aim of this national survey of Australian adults living with type 1 or type 2 diabetes was to assess the psychosocial aspects of living with diabetes. Diabetes MILES – Australia represented a major achievement in the study of diabetes in Australia, as it was the first time that the psychological health, behavioural diabetes management, social impacts, and unmet needs of a large and diverse national sample were assessed, providing a baseline against which the results of future studies can be compared.

The findings of the 2011 Diabetes MILES – Australia study have been disseminated widely in journal articles, at national and international conferences, at health professional training days and community seminars. Publications have addressed a diverse range of topics including

psychological insulin resistance amongst adults with type 2 diabetes[30-32]; subjective well-being[33] and suicidal ideation[34] amongst adults with type 1 or type 2 diabetes; measurement of diabetes distress[35]; the relationships between healthcare access and self-management and self-efficacy[36], economic hardship[37], and rural/regional living[38]; and the challenges faced by specific groups such as young adults with type 2 diabetes[39] and severely obese adults with type 2 diabetes[40-42]. Collectively, the findings from the 2011 Diabetes MILES – Australia survey have provided crucial evidence to inform policy, practice and service delivery for adults with type 1 and type 2 diabetes in Australia. The Diabetes MILES Study is now an international collaborative, with a similar survey having been conducted in The Netherlands[43]. Diabetes MILES-Youth, a national survey of Australian adolescents with diabetes (aged 12-18 years) and their parents, was conducted in 2014[44].

While the 2011 Diabetes MILES – Australia study provided a valuable 'snapshot', this cross-sectional survey does not allow assessment of change over time, or associations between exposure to a new condition (e.g. commencement of insulin therapy) and key outcomes (e.g. emotional well-being and treatment self-efficacy). Diabetes treatments, programs and services are continually developing and advancing[45], and ongoing survey research at a national level will enable us to track psychosocial well-being and self-management behaviour in parallel with these changes. Further, as psychosocial research in diabetes gains traction and the field expands, new avenues of investigation have been identified and novel topics of interest have emerged. Examples include stigmatisation of, and discrimination against, people with diabetes[5, 46, 47], memory and cognition[48], and self-compassion[49]. To date, there is little to no population-based data on these important topics in relation to diabetes.

To fill these gaps, we conducted the second Diabetes MILES – Australia (MILES-2) study. In this paper, we detail the methods and cohort profiles of the MILES-2 survey participants. This study had two elements, each with different aims:

1. longitudinal cohort: a follow-up survey of the 2011 Diabetes MILES – Australia participants to allow assessment of change over time in, and prospective investigation of, key psychological and behavioural outcomes. The longitudinal data will enable exploration of key topics, such as:
    a. potential impact of changes in treatment (e.g. initiation of insulin therapy) and/or self-care regimen (e.g. changes in glucose monitoring behaviours) on diabetes-specific distress;
    b. the psychological (e.g. illness beliefs, anxiety, depression) and behavioural (e.g. healthcare visits, diabetes self-care) antecedents of diabetes complications (e.g. diabetic retinopathy);
    c. prospective predictors of the development of psychological problems (e.g. depressive or anxiety symptoms) or diabetes complications.

2. 2015 new cohort: a cross-sectional survey of a new national sample of adults with type 1 or type 2 diabetes to introduce novel, emerging topics of investigation. These new cross-sectional data will enable exploration of novel topics, such as:
    a. perceived and experienced diabetes stigma and weight stigma, and their associations with key psychological problems (e.g. depressive symptoms) and behavioural issues (e.g. medication-taking and blood glucose monitoring);

b. the relationship between prospective memory (i.e. remembering to perform a planned action) and diabetes self-care behaviours;
c. the relationship between self-compassion and the experienced emotional burden of diabetes (e.g. diabetes-specific distress).

COHORT DESCRIPTIONS

Study design and setting

The MILES-2 survey (both for the longitudinal cohort and the 2015 new cohort) was conducted primarily online, although a hard copy version was made available for those who requested it (e.g. due to not having access to, or not knowing how to use, the internet). The study was conducted and is reported according to the Checklist for Reporting Results of Internet E-Survey (CHERRIES, see Appendix 1)[50].

The survey content and procedure used for the longitudinal and new cohorts were near identical. The methods described below refer to both cohorts unless specified otherwise.

Ethics approval and consent

Ethics approval was granted by the Deakin University Human Research Ethics Committee (reference number: 2011-046). All participants provided informed consent, having read a plain language description of the study, using a tick-box form (electronic or in hard copy).

Participant eligibility and recruitment

Eligible participants were adults (aged 18-75 years) living in Australia who had type 1 or type 2 diabetes, and were proficient in English for the purposes of reading and completing the survey (as it was available in English only). People with other types of diabetes (e.g. gestational, Mature Onset Diabetes of the Young (MODY), Latent Autoimmune Diabetes in Adults (LADA)) were not eligible to take part because the survey content was not tailored to address issues specific to these special groups. Similarly, people under the age of 18 and over the age of 75 were not eligible for participation because the survey content and format were likely to be inappropriate for these groups; and, in the case of those under 18 years, so as not to duplicate the efforts of the recent Diabetes MILES Youth survey[44].

Longitudinal cohort recruitment

Of the 3,833 respondents to the 2011 Diabetes MILES – Australia survey, 2,153 (56%) consented to being invited to take part in future longitudinal cohort studies and provided complete email or postal addresses to facilitate contact. Invitations were sent by email where possible (n=1,643), with postal invitations sent initially to only 510 participants who did not provide an email address. An additional 338 invitations were sent by post after email bounce-backs were received. Overall, 88 participants were not contactable by email or post (invitation returned to sender). Thus, 2,065 participants of the 2011 survey received an invitation to take part in the MILES-2 survey; a single reminder email/letter was sent three weeks later.

2015 new cohort recruitment

The National Diabetes Services Scheme (NDSS) registrant database was used to contact potential participants. The NDSS, an initiative of the Australian Government administered by Diabetes Australia, provides subsidised products, information and support services for Australians with diabetes. Most Australians diagnosed with diabetes are registered with the

scheme. Of the 1.2 million NDSS registrants[51], approximately 47% have indicated consent to be contacted about research participation opportunities. Of these, a stratified random sample of 20,000 registrants were sent a postal invitation directly by the NDSS (i.e. researchers did not have access to the database), which directed them to the online survey website and provided researcher contact details. The sample was stratified according to population in each Australian state, and as follows:

- 8,000 with type 1 diabetes (40% of the total sample)
- 12,000 with type 2 diabetes (60% of the total sample); 6,000 of whom registered as using insulin (50% of type 2 diabetes sample)

Adults with type 1 diabetes and with type 2 diabetes using insulin were purposefully over-sampled to ensure adequate representation of these sub-samples. The sample was not stratified by gender.

To ensure the sample was indeed a new cohort of participants, registrants who were randomly sampled during recruitment for the 2011 Diabetes MILES – Australia survey were excluded from the 2015 sampling. Finally, the study was also advertised nationwide in diabetes-related media (e.g. magazines, e-newsletters, social media).

Data collection and handling procedure

Potential participants were directed to the study website[52] which presented a plain language description of the study and an online consent form. Those who provided informed consent were directed through to the eligibility screening. Ineligible participants were screened out automatically and presented with a message thanking them for their interest and advising they were not eligible to take part. Eligible participants were directed through to the survey proper. At the end of the survey, all respondents were invited to provide their email address to facilitate one or more of the following: 1) entry into a prize draw (chance to win one of three iPad minis™), 2) to receive a free electronic copy of the study report, 3) to receive notifications about future research opportunities, 4) to withdraw data at a later date. Provision of an email address was voluntary, and participants could select to which of the four options they consented.

The MILES-2 survey was hosted by Qualtrics™, a secure, online survey platform. The survey was open for participation for seven weeks (23 March – 11 May 2015). As participants progressed through the survey, their data were saved automatically by Qualtrics™.

All online survey responses (complete and incomplete) were logged by the Qualtrics™ survey platform and downloaded at survey close into data files for analysis in Statistical Package for the Social Sciences (SPSS) (IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp). Hard copy survey responses were entered manually into the SPSS data file by one researcher, and checked for accuracy by a second researcher. Contact details were extracted from the main data file and stored separately in a password-protected folder. Longitudinal cohort participants' 2015 data were matched with their existing 2011 data using the unique log-in code provided, and by validating the match against diabetes type, age and gender.

A total of 2,651 survey responses were recorded by Qualtrics™. However, 148 duplicate cases were identified in the data file (using a combination of IP address and demographic/clinical data

such as age, gender, postcode, and diabetes type) and deleted. The main reasons for duplicate cases were:

a) participants who were screened out at the eligibility assessment phase restarted the survey to answer the screening questions in a different way (e.g. changing diabetes type response from 'MODY' to 'type 2 diabetes'), allowing them to unlock the full survey. In these instances, their second attempt was deleted and their data were not included in any analysis due to ineligibility.
b) participants who lost their internet connection or their responses failed to save, and they restarted the survey in order to complete it. In these instances, the most complete entry was retained and the other deleted. If there was no difference in the amount of data available in each case, the first entry was retained.

Response rate

A total of 2,503 unique consenting responses (27 hard copy completions) to the MILES-2 survey were identified, including 2015 new cohort (n=1,970) and longitudinal cohort (n=533) respondents. The response rates for these separate sub-samples are discussed separately below.

The **2015 new cohort** participants who passed the eligibility screening (n=1,829, 93%) had the opportunity to indicate how they heard about the survey. Seventy-nine per cent (n=1,453) of this subsample indicated that they received a letter from the NDSS inviting them to take part, indicating a response rate of 7% of the 20,000 NDSS registrants who received an invitation. Extrapolating this rate to also include those screened out due to ineligibility, the estimated total response rate to the NDSS mail-out is 8%.

Of the 2,065 participants of the original 2011 survey, who indicated willingness to be contacted about similar studies in the future, 533 (26%) participated, and are referred to hereafter as the **longitudinal cohort**. Reasons for non-participation are not known.

Final eligible samples and their characteristics

Of the 2,503 unique respondents, 161 were screened out due to ineligibility. The final cross-sectional sample included N=2,342 eligible participants, comprising n=1,838 2015 new cohort participants and n=504 longitudinal cohort participants. Full sample characteristics are presented in Table 1.

In the final sample, 46% had type 1 diabetes and 54% had type 2 diabetes. Overall, men and women were represented equally (50% versus 50%). Unsurprisingly, participants with type 2 diabetes were substantially older than participants with type 1 diabetes (mean difference: 17 years), but reported shorter diabetes duration (mean difference: 8 years). Amongst those with type 1 diabetes, 35% were managing their diabetes with an insulin pump. Amongst those with type 2 diabetes, 42% were using insulin. Most respondents spoke English as their main language (97%), were married or in a de facto relationship (68%), had vocational or university qualifications (66%), lived in metropolitan areas (61%), were in paid employment (54%), and had an annual household income of more than AU$40,000 per annum (54%).

Table 1: Sample characteristics for the 2015 Diabetes MILES – Australia survey, by diabetes type*

	Type 1 diabetes n=1,078 (46)	Type 2 diabetes n=1,264 (54)	Total sample N=2,342 (100)
Gender - female	639 (59)	539 (43)	1178 (50)
Age - years	44±15 (18-75)	61±9 (22-75)	53±15 (18-75)
Diabetes duration - years	19±14 (0-68)	11±7 (0-44)	15±12 (0-68)
Primary diabetes management			
Insulin pump therapy	380 (35)	2 (0.2)	382 (16)
Insulin injections	698 (65)	529 (42)	1227 (52)
Non-insulin injectables	-	47 (4)	47 (2)
Blood glucose lowering tablets	-	510 (40)	510 (22)
Diet and/or exercise alone	-	176 (14)	176 (8)
Aboriginal or Torres Strait Islander	14 (1)	22 (2)	36 (2)
Main language spoken at home - English	1054 (98)	1214 (96)	2268 (97)
Country of birth - Australia	831 (77)	889 (70)	1720 (73)
Relationship status			
Single	241 (22)	111 (9)	352 (15)
In a steady relationship	52 (5)	21 (2)	73 (3)
Married or De-Facto	706 (66)	891 (71)	1597 (68)
Separated	18 (2)	36 (3)	54 (2)
Divorced	48 (4)	130 (10)	178 (8)
Widowed	8 (1)	71 (6)	79 (3)
Education			
No qualifications	30 (3)	125 (10)	155 (7)
School/Intermediate certificate	105 (10)	205 (16)	310 (13)
High School/Leaving certificate	181 (17)	140 (11)	321 (14)
Trade training or diploma(s)	252 (23)	382 (30)	634 (27)
University undergraduate degree	269 (25)	223 (18)	492 (21)
Higher university degree	236 (22)	185 (15)	421 (18)
(Un)Employment details			
Paid employment	770 (72)	477 (38)	1247 (54)
Retired	146 (14)	579 (46)	725 (31)
Full-time student	26 (2)	8 (1)	34 (2)
Unpaid household duties	40 (4)	49 (4)	69 (3)
Unemployed	86 (8)	146 (12)	232 (10)
Other	8 (1)	4 (0.3)	12 (1)
Annual household income ($AUD)			
≤20,000	130 (12)	225 (18)	355 (15)
20,001 – 40,000	123 (12)	281 (23)	404 (17)
40,001 – 60,000	135 (13)	199 (16)	334 (14)
60,001 – 100,000	240 (23)	175 (14)	415 (18)
100,001 – 150,000	158 (15)	113 (9)	271 (12)
>150,000	123 (12)	75 (6)	198 (9)
Don't know / prefer not to say	155 (15)	177 (14)	332 (14)
State			
Australian Capital Territory	54 (5)	132 (10)	186 (8)
New South Wales	345 (32)	258 (20)	603 (26)
Northern Territory	9 (0.8)	41 (3)	50 (2)
Queensland	140 (13)	143 (11)	283 (12)

South Australia	86 (8)	120 (10)	206 (9)
Tasmania	50 (5)	120 (10)	170 (7)
Victoria	281 (26)	297(24)	578 (25)
Western Australia	113 (10)	151 (12)	264 (11)
Geographical location			
Metropolitan	483 (63)	750 (60)	1433 (61)
Regional	272 (25)	303 (24)	575 (25)
Rural	122 (11)	206 (16)	328 (14)

Data are n (%) or mean±SD (range)

* Total N reported is not always consistent with total sample size due to missing data for some variables. Percentages do not always sum to 100 due to rounding.

Table 2 compares the sample characteristics of the longitudinal and 2015 new cohorts. With few exceptions, the longitudinal and new cohorts were equivalent on key socio-demographic and clinical characteristics, indicating that the cohorts may be pooled for future analyses. On average, participants with type 1 diabetes in the longitudinal cohort were older and had a longer diabetes duration than the new cohort, but while the difference was significant, it was not notable (<5 year mean difference in both instances). Respondents with type 1 diabetes in the longitudinal cohort were more likely to be using an insulin pump than those in the new cohort. Regardless of diabetes type, compared with the new cohort, the longitudinal cohort was more likely to have a university education, less likely to have no qualifications, and more likely to reside in the state of Victoria.

Table 2: Sample characteristics by cohort*

	Longitudinal Cohort	**2015 new Cohort**	**Sig**
Total eligible sample	**504 (22)#**	**1838 (79)**	
Gender - female	261 (52)	917 (50)	ns
Diabetes type			ns
Type 1 diabetes	236 (47)	842 (46)	
Type 2 diabetes	268 (53)	996 (54)	
Age - years			
Type 1 diabetes	47±14	43±16	<.001
Type 2 diabetes	62±8	61±10	ns
Diabetes duration - years			
Type 1 diabetes	22±14	18±14	<.001
Type 2 diabetes	12±7	11±8	ns
Primary treatment for type 1 diabetes			
Insulin pump therapy	106 (45)	274 (33)	<.001
Insulin injections	130 (55)	568 (67)	
Primary treatment for type 2 diabetes			
Insulin pump therapy	0 (0)	2 (0.2)	
Insulin injections	95 (35)	434 (44)	
Non-insulin injectables	11 (4)	36 (4)	ns
Blood glucose lowering tablets	119 (44)	391 (39)	
Diet and/or exercise alone	43 (16)	133 (13)	
Aboriginal or Torres Strait Islander origin	5 (1)	31 (2)	ns
Main language spoken at home - English	494 (98)	1774 (97)	ns
Country of birth - Australia	387 (77)	1333 (73)	ns
Relationship status			

Single	64 (13)	288 (16)	
In a steady relationship	12 (2)	61 (3)	
Married or De-Facto	356 (71)	1241 (68)	ns
Separated	12 (2)	42 (2)	
Divorced	44 (9)	134 (7)	
Widowed	15 (3)	64 (3)	
Education			
No qualifications	15 (3)	140 (8)	
School/Intermediate certificate	68 (14)	242 (13)	
High School/Leaving certificate	58 (12)	263 (14)	<.001
Trade training or diploma(s)	132 (26)	502 (28)	
University undergraduate degree	123 (25)	369 (20)	
Higher university degree	106 (21)	315 (17)	
(Un)Employment details			
Paid employment	280 (56)	967 (53)	
Retired	155 (31)	570 (31)	
Full-time student	6 (1)	28 (2)	ns
Unpaid household duties	26 (5)	63 (3)	
Unemployed	35 (7)	197 (11)	
Other	2 (0.4)	10 (1)	
Annual household income ($)			
≤20,000	67 (13)	288 (16)	
20,001 – 40,000	79 (16)	325 (18)	ns
40,001 – 60,000	80 (16)	254 (14)	
60,001 – 100,000	94 (19)	321 (18)	
100,001 – 150,000	61 (12)	210 (12)	
>150,000	57 (11)	141 (8)	
Don't know / prefer not to say	65 (13)	267 (15)	
State			
Australian Capital Territory	17 (3)	169 (9)	
New South Wales	105 (21)	498 (27)	
Northern Territory	1 (0.2)	49 (3)	
Queensland	81 (16)	202 (11)	<.001
South Australia	25 (5)	181 (10)	
Tasmania	12 (2)	158 (9)	
Victoria	215 (43)	363 (20)	
Western Australia	47 (9)	217 (12)	
Geographical location			
Metropolitan	312 (63)	1121 (61)	
Regional	127 (25)	448 (24)	ns
Rural	63 (13)	265 (14)	

Data are n (%) or mean±SD (range)

*Table refers only to eligible participants. Total N reported is not always consistent with total sample size due to missing data on some items. Percentages do not always sum to 100 due to rounding.

#Of the 504 longitudinal cohort participants, 459 could be matched with 2011 data.

Depth and breadth of available data

Consistent with the aims of the Diabetes MILES Study initiative, the data available primarily relate to the psychological (e.g. emotional well-being), behavioural (e.g. self-management) and social (e.g. diabetes stigma) aspects of living with diabetes. These data make possible the assessment of prevalence, relationships between key variables, and (in the longitudinal cohort), change over time and associations between exposure to a new condition and key outcomes.

The survey included validated scales, study-specific individual items and newly developed measures (for validation). For 'core' constructs (e.g. general and diabetes-specific emotional well-being), the measures used in 2011 were included in the 2015 survey. This was important in order to generate a longitudinal data set for assessing within-group change over time, but also to enable comparison on key issues of the full 2011 and 2015 study samples as representative 'snapshots' of the Australian population of adults with diabetes.

While the 2011 and 2015 surveys had similar content, they were not identical. Some measures (e.g. Resources and Support for diabetes Self Management questionnaire) were not repeated in 2015 because ongoing data collection on the topic was not considered a key priority. Some measures were replaced with another measure of the same construct (e.g. the Diabetes Self-Care Inventory – Revised was replaced with the Summary of Diabetes Self-Care Activities[53]). Some measures were replaced with a shorter version to reduce respondent burden (e.g. the Quality of Life Questionnaire was replaced with the DAWN Impact of Diabetes Profile[5]). Finally, some measures were replaced with measures tailored to diabetes type and/or treatment (e.g. the Diabetes Empowerment Scale Short-Form[54] was replaced with the Confidence in Diabetes Self-care scale, with insulin-using[55] and non-insulin using[56] versions.

In the original (2011) Diabetes MILES study, two alternate survey versions (A and B) were used. To ensure that all longitudinal cohort participants had complete data sets for key variables (e.g. diabetes-specific distress), their 2015 survey content was tailored automatically (based on the unique code they entered) to match the survey version they completed in 2011. However, this automatic tailoring was not possible for those completing the hard copy surveys (n=27), and thus they were treated as new cohort participants.

Survey content was grouped by theme into eight sections: 1) Demographics, 2) My General Well-being, 3) My Feelings about Diabetes, 4) My General Health, 5) Support from Health Professionals, Family and Friends, 6) My Diabetes, 7) My Blood Glucose Levels, 8) My Thoughts and Beliefs. It was also tailored to diabetes type and treatment (based on information provided in the Demographics section of the survey) and as such, not all measures were presented to every participant. Table 1 summarises the topics/constructs, variables and measures used in the 2015 MILES-2 survey (for both the new and longitudinal cohorts separately), and also indicates which of the same content was included in the 2011 survey.

Table 3. Survey content for the 2015 Diabetes MILES – Australia survey

Concept/topic	Measure or variable	2015 new cohort	Longitudinal cohort	2011 survey
Demographics				
Eligibility screen	Diabetes type, age, live in Australia	✓	✓	✓
Demographic & socioeconomic details	Gender, state, postcode, country of birth, language, marital status, living situation, income, employment, education			
Diabetes details	Diabetes duration, diabetes treatment			
Other	Diabetes organisation membership, how they heard about survey			
My General Well-being				
General emotional well-being	World Health Organisation Well-being Index (WHO-5)[57]	✓	✓	✓
	General life satisfaction (single item)[58]			
Depressive symptoms	Patient Health Questionnaire (PHQ-8)[59]			
Anxiety symptoms	Generalised Anxiety Disorder scale (GAD-7)[60]			
My Feelings About Diabetes				
Diabetes-specific distress	Problem Areas In Diabetes Scale (PAID)[61]	✓	✓*	✓*
	Diabetes Distress Scale (DDS)[62]		✓^	✓^
	Type 1 Diabetes Distress Scale (T1-DDS)[63]		✓^#	
Diabetes-related and generic stigma	Type 1 and Type 2 Diabetes Stigma Assessment Scales (DSAS-1; DSAS-2)	✓	✓*	
	Stigma Scale for Chronic Illnesses – 8 item version (SSCI-8)[64]	✓	✓*	
	6 study-specific items about portrayal of diabetes in the media	✓	✓	
Quality of life	DAWN Impact of Diabetes Profile (DIDP)[5]	✓	✓	
Illness centrality	Centrality Scale[65]	✓	✓	
My General Health				
Health background	Physical and mental health comorbidities and complications, height and weight, smoking status, health insurance and pension	✓	✓	✓
Weight stigma	Weight Self-Stigma Questionnaire (WSSQ)[66]	✓	✓	
Memory	Prospective and Retrospective Memory Questionnaire (PRMQ)[67]	✓	✓	
Support from Health Professionals, Family and Friends				
Healthcare	Access to providers in last 12 months, main provider, group structured education	✓	✓	✓
Social support	Diabetes Support Scale (DSS)[68]	✓	✓	
	Social Support subscale of Diabetes Care Profile (DCP)[69]	✓	✓	
Peer support	Study-specific items	✓	✓	
My Diabetes				
Self-care	Diet and physical activity subscales of the Summary of Diabetes Self-Care Activities (SDSCA)[53]	✓	✓	
	Study-specific items: dietary behaviours	✓	✓	
	Study-specific items: physical activity behaviours	✓	✓	
	Study-specific items: blood glucose	✓	✓	

	monitoring			
	Modified Importance and Burden items (for diet, physical activity, blood glucose monitoring) from the Summary of Diabetes Self-Care Inventory – Revised (unpublished)	✓	✓	
Diabetes treatment	Study-specific items assessing frequency/time of day for injections/bolusing, frequency of forgetting and skipping injections/bolus/medication dose, reasons for forgetting/skipping	✓	✓	
HbA1c	Study-specific items	✓	✓	✓
App use for self-management support	Study-specific items	✓	✓	
Diabetes-specific self-efficacy	Confidence In Diabetes Self-Care (CIDS) (insulin-using[55] and non-insulin-using versions[56])	✓	✓	
Psychological insulin resistance	Insulin Treatment Appraisal Scale (ITAS)[70]	✓~	✓~	✓~
	'Willingness to begin insulin' single item[71]	✓~	✓~	
My Blood Glucose Levels				
Hyperglycaemia	Two items adapted from the Hyperglycaemia Avoidance Scale (HAS)[72]	✓#	✓#	
Hypoglycaemia	Study-specific items (some based on the Hypoglycaemia Awareness Questionnaire[73]) to assess frequency, hospitalisation, insulin adjustment in response to hypoglycaemia, impaired awareness of hypoglycaemia	✓	✓	✓
	Edinburgh Hypoglycaemia Survey (EHS)[74]	✓	✓	
	Gold Score[75]	✓	✓	✓
My Thoughts and Beliefs				
Self-esteem	Rosenberg Self-Esteem Scale (RSE)[76]	✓	✓	
Self-compassion	Self-Compassion Scale Short Form (SCS-SF)[77]	✓	✓	
Other	Free-text box inviting participants to make any other comments	✓	✓	✓

*Participants who completed survey B version in 2011 only. ^Participants who completed survey A version in 2011 only. #Participants with type 1 diabetes only. ~Participants with type 2 diabetes only.

FINDINGS TO DATE

Sample stratification

The success of the stratified sampling approach was assessed by comparing the sub-sample of new cohort respondents who indicated that they received an invitation direct from the NDSS against the planned stratification (described in Methods). Respondents with type 1 diabetes were slightly over-represented in the new cohort (45%) relative to the planned stratification (40% type 1 diabetes, 60% type 2 diabetes). Relative to the planned stratification for state (designed to reflect the proportion of NDSS registrants per state), there was evidence of over-sampling of participants in the Australian Capital Territory (3% invited versus 11% response), New South Wales (21% versus 26%), the Northern Territory (1% versus 3%) and Tasmania (3% versus 10%). Under-sampling of participants was evident in Queensland (19% invited versus

12% response), South Australia (16% versus 11%), Victoria (20% versus 15%), and Western Australia (17% versus 12%). Respondents with insulin-treated type 2 diabetes were under-represented in the new cohort relative to the stratified sampling (42% invited versus 50% response).

Longitudinal cohort data matching

Of the 504 eligible participants who completed the longitudinal cohort survey, 459 (91%) were matched with their original 2011 data. The representativeness of the longitudinal dataset compared to the original 2011 sample can be assessed by comparing the sample characteristics of those who took part in both 2011 and 2015 with those who took part in 2011 only. As shown in Table 4, participants who completed both the 2011 and 2015 surveys were slightly more likely than those completing the 2011 survey only to have type 1 diabetes, report a higher education and annual income, and live in metropolitan regions of Australia. For those with type 1 diabetes, those who participated in both the 2011 and 2015 surveys had a longer mean diabetes duration relative to those who took part in 2011 only. Among those with type 2 diabetes, the reverse was true: participants of both the 2011 and 2015 surveys had a shorter mean diabetes duration compared to those who took part in 2011 only.

Table 4: Baseline characteristics of longitudinal survey completers (2015 and 2011) versus non-completers (2011 only) *

	2011 only (cross-sectional) cohort	2011 & 2015 (longitudinal) cohort	Sig
TOTAL	**2879 (86)**	**459 (14)**	
Gender - female	1538 (54)	240 (53)	ns
Diabetes type			
Type 1 diabetes	1157 (40)	219 (48)	.002
Type 2 diabetes	1722 (60)	240 (52)	
Age - years			
Type 1 diabetes	42±14	43±13	ns
Type 2 diabetes	59±9	57±8	.016
Diabetes duration - years			
Type 1 diabetes	15±13	18±14	.001
Type 2 diabetes	9±7	8±6	.030
Primary treatment for type 1 diabetes			
Insulin pump therapy	246 (21)	79 (36)	<.001
Insulin injections	902 (79)	140 (64)	
Primary treatment for type 2 diabetes			
Insulin pump therapy	8 (0.0)	0 (0)	
Insulin injections	642 (39)	72 (30)	
Non-insulin injectables	15 (1)	7 (3)	.002
Blood glucose lowering tablets	767 (45)	109 (45)	
Diet and/or exercise alone	266 (16)	52 (22)	
Aboriginal or Torres Strait Islander origin	47 (2)	2 (0.0)	.037
Main language spoken at home - English	2759 (97)	446 (98)	ns
Country of birth - Australia	2119 (74)	354 (77)	ns
Relationship Status			
Single	391 (14)	59 (139)	

In a steady relationship	105 (4)	20 (4)	ns
Married or De-Facto	1945 (69)	325 (71)	
Separated	77 (3)	6 (1)	
Divorced	216 (8)	39 (9)	
Widowed	89 (3)	7 (2)	
Education			<.001
No qualifications	254 (9)	12 (3)	
School/Intermediate certificate	308 (11)	34 (8)	
High School/Leaving certificate	552 (20)	79 (18)	
Trade training / certificate/ diploma	848 (31)	135 (30)	
University undergraduate degree	474 (18)	108 (24)	
Higher university degree	271 (10)	81 (18)	
In paid employment	1654 (57)	310 (68)	<.001
Annual household income ($)			<.001
≤20,000	539 (20)	57 (13)	
20,001 – 40,000	500 (19)	59 (13)	
40,001 – 60,000	502 (19)	79 (18)	
60,001 – 100,000	579 (21)	120 (27)	
100,001 – 150,000	346 (13)	81 (18)	
>150,000	228 (8.)	52 (12)	
Geographical location			<.001
Metropolitan	1425 (51)	275 (61)	
Regional	808 (29)	116 (26)	
Rural	587 (21)	63 (14)	

Data are n (%) or mean±SD (range)
*Data from 2011 Diabetes MILES – Australia.

Qualitative findings

The qualitative data provided by participants in the free-text boxes indicated that in general, the survey was highly acceptable to participants. While some participants felt the survey was *"too long"*, others were appreciative for the *"comprehensive"* and *"thoughtful"* nature of this research. For many, it promoted further learning about diabetes, and a chance to reflect on their attitudes to living with diabetes:

> "*Doing this survey makes me realise that I could access support networks/ forums/ health care practitioners more than I actually do"* (woman, 31 years, type 1 diabetes)

Some participants perceived that *"psychological support doesn't exist"* (woman, 25 years, type 1 diabetes) for their diabetes-related concerns, and therefore were pleased that this work was being conducted:

> *"I would like to say thank you for this survey, as it's good to know that there are people concerned with diabetes and the issues we may have"* (man, 67 years, type 2 diabetes)

STRENGTHS AND LIMITATIONS

Strengths

Key strengths of MILES-2 are the breadth and depth of quantitative data and the large, population-based sample size that affords the statistical power to investigate sub-groups and conduct multivariate analyses. While clinical and biomedical research abounds in the field of diabetes, there is a pressing need for an increased research focus on the psychosocial aspects of the condition[27]. MILES-2 contributes to this gap in our knowledge by providing a rich dataset that combines cross-sectional and longitudinal assessment of key topics such as emotional well-being, self-management, and healthcare access, as well as introducing novel topics of investigation such as social stigma, cognition and memory, and self-compassion. The qualitative feedback from participants indicated that the topics included in the survey were relevant to them, and the survey was generally very well received.

The survey was conducted primarily online, with only 27 of the 2,342 respondents (1%) asking to complete a hard copy version. The online survey methods were successful in generating a sample with gender balance, a wide age range, diverse socio-economic backgrounds, and a representative mix of people living in metropolitan, regional, and rural areas in all states and territories of Australia. The online survey was a successful and economical approach to surveying a wide range of Australian adults with diabetes, all within a relatively short time period (seven weeks).

The significance of the emerging longitudinal dataset is particularly noteworthy. For the first time, it will be possible to explore predictors and consequences of psychological distress and sub-optimal behavioural diabetes management in a non-clinical, population-based sample. It represents the first attempt to track the natural trajectory of emotional problems in people with diabetes (e.g. diabetes distress) and to investigate any social, economic, and/or demographic factors that may contribute to variation in psychological experiences. This in turn will enable better tailoring of interventions to meet those with greatest need. It is our intention to conduct further surveys in the future to continue to follow all respondents who have indicated willingness to continue their participation. This will enable us to build on the existing longitudinal dataset using a third wave of data collection, and to increase the sample size and breadth of survey topics available in the longitudinal cohort.

Limitations

Response rates

The response rates for both the longitudinal and the new cohorts in the MILES-2 survey were low; the longitudinal cohort had a markedly better response rate (26%) than the 2015 new cohort (8%). It is possible that respondents who agreed to take part in future surveys in 2011 had a higher level of commitment to and interest in the Diabetes MILES Study due to their previous participation.

In the longitudinal cohort, substantial attrition was evident between the 2011 and 2015 surveys, and the response rate is notably lower than other health-related longitudinal Australian surveys[78, 79]. However, these other initiatives were very well resourced, enabling many repeat attempts at contact using various methods. For MILES-2, only two contacts were possible (invitation plus one reminder). Further, MILES-2 focused specifically on adults with type 1 or

type 2 diabetes aged 18-75, whereas in contrast, the other initiatives sampled the general population and did not focus on a particular condition. It has been noted that the population being sampled is the most important determining factor for survey response rates[80], and thus comparison of the MILES-2 response rate with other Australian general population surveys is not necessarily appropriate. People with diabetes are more likely than the general population to have serious physical and mental health comorbidities[12, 13, 81, 82], impaired general well-being[33], and those with type 2 diabetes are more likely to be socioeconomically disadvantaged[83], making non-response and problematic attrition more likely[84, 85].

Another possible explanation for the relatively high rate of attrition between the 2011 and 2015 surveys is the different methods of recruitment and data collection. In 2011, participants received a hard copy survey; online survey completion was possible but 70% of 2011 survey respondents completed the hard copy version. In contrast, the 2015 survey was online by default, and respondents needed to request a hard copy. This may have created too many barriers to participation for some, leading to non-response.

The response rate of the 2015 new cohort is low at 8%, and considerably lower than the 18% observed in the 2011 survey[29]. However, a number of factors may explain this. First, as noted above, the default online data collection may have been a barrier to participation. Second, the survey took place at a time when NDSS registrants were being contacted frequently for research purposes, which was not the case in 2011. On the advice of the NDSS, the survey launch date was pushed back from November 2014 to March 2015 in an attempt to avoid survey fatigue. However, the low response rate suggests that this delay was insufficient and that NDSS registrants may have been burdened by too many research participation requests. Finally, online surveys are now prolific, and decreasing response rates have been noted elsewhere[80]. Thus, the low response rate observed in the 2015 new cohort of the MILES-2 survey may be reflective of a broader trend, compounded by the challenges faced by this population as already described.

In spite of the low response rates, as noted above, the samples are relatively representative and the sample sizes obtained are more than adequate to facilitate inferential data analyses, and to draw conclusions about the unmet needs of Australian adults with type 1 and type 2 diabetes.

Stratification of the new cohort sample

The sampling for the new cohort was stratified by diabetes type, insulin use (type 2 diabetes only), and Australian state of residence. Respondents with type 1 diabetes were slightly over-represented in our sample (45%) relative to the stratification (40%). This may reflect a generally higher level of engagement in diabetes-related activities and advocacy in this group relative to those with type 2 diabetes.

Amongst respondents with type 2 diabetes, 42% were using insulin which is almost double the proportion observed on the NDSS database (24%), but less than anticipated given the purposeful sampling stratification (50%). Based on our previous research, Australian adults with type 2 diabetes who use insulin (compared with those not using insulin) have a longer diabetes duration[86], are more likely to have at least one diabetes-related complication[31, 32], and are more likely to have depressive and anxiety symptoms[86]. These factors may make them less likely to engage in research initiatives[84, 85].

Sample representativeness

Notwithstanding the purposeful stratification and oversampling of adults with type 1 diabetes and those with insulin-treated type 2 diabetes, the gender balance was broadly representative of people registered on the NDSS database[87]. Overall, men and women were represented equally in the sample (50% men; 50% women) and the proportions in our sample approximate the NDSS register (52% men versus 48%).

Amongst those with type 1 diabetes, 35% were using an insulin pump to manage their diabetes. As only 10% of adults with type 1 diabetes registered with the NDSS use an insulin pump [88], it appears that this group is over-represented in our sample. While insulin pump users were intentionally over-sampled in the 2011 survey this was not the case for the 2015 new cohort, and yet they were over-represented in the sample anyway. The over-representation of pump users is consistent with research participation patterns observed in similar studies[43, 44]. Pump users may be more engaged in research because they perceive themselves to benefit from advances in knowledge, or it may be reflective of the fact that pump users tend to be more highly educated and from higher socio-economic backgrounds relative to non-pump users[88].

Compared with the Australian general population, our sample was more likely to speak English as their main language[89], to be married or in a de facto relationship[90], to be in paid employment[91], and have post-high school qualifications[92]. This indicates that those who took part are a relatively privileged sample with significant social resources who are likely to have better health literacy and access to health services than Australians with diabetes generally. This self-selection bias has been observed in many web-based studies[93, 94], and may result in the under-estimation of social and emotional problems, and problems of healthcare access. However, a key focus of future inferential analyses of the MILES-2 data will be the relationships between variables, and the self-selection bias is likely to have minimal impact on this.

CONCLUSIONS AND COLLABORATIONS

The second Diabetes MILES – Australia study builds on the previous Diabetes MILES Study initiatives to deliver Australia's first large-scale longitudinal assessment of the psychosocial aspects of type 1 and type 2 diabetes, and to introduce novel topics of investigation at a population level.

The depth and breadth of the data available in this large sample will raise further awareness of the psychosocial impact of living with type 1 and type 2 diabetes, will highlight unmet needs and priority areas for future investigation, and crucially, will inform policy, program and intervention development and evaluation. The findings from MILES-2 will be disseminated through academic publications, conference presentations, health professional training and community symposia over several years.

We encourage collaborations from researchers with relevant expertise in the field. Researchers may gain access to the second Diabetes MILES – Australia survey dataset upon submission of a proposal detailing the topics of interest, key research questions, and hypotheses. Proposals will

be evaluated by the Diabetes MILES Study research team on the basis of feasibility, relevance, novelty, and expertise of the researchers. Enquires should be directed to Dr Jessica Browne (first author).

FURTHER DETAILS

Ethics approval and consent to participate

This study was approved by the Deakin University Human research Ethics Committee (2011-046). All participants provided informed consent.

Data sharing statement

The second Diabetes MILES – Australia survey dataset is available for analysis by researchers with interest and expertise in this field. For further information, please contact: jbrowne@acbrd.org.au

Competing interests

All authors have completed the ICMJE uniform disclosure at www.icmje.org/coi_disclosure.pdf and declare: financial support for the submitted work from Sanofi ANZ in the form of an unrestricted educational grant; JB has done consultancy work for Sanofi ANZ, has served on a Sanofi ANZ advisory board, and has had travel expenses covered by Sanofi ANZ, with all monies given to her institution. FP has served on an advisory board for Sanofi-Aventis, with monies paid to him personally. JS has done consultancy work for Sanofi ANZ and has had travel expenses covered by Sanofi ANZ, with all monies paid to her institution. EHT, ADV, and CH have no relevant conflicts of interest to declare.

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Author's contributions

JS conceived The Diabetes MILES Study, and together with FP developed The Diabetes MILES Study International Collaborative. All authors contributed to the development of the study design and survey content. JB project managed MILES-2, and wrote the first draft of this manuscript with substantial input from EHT. All authors provided substantial intellectual contributions to the manuscript by providing feedback on drafts. All authors approved the final manuscript.

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Appendix 1. CHERRIES checklist for MILES-2 online survey

Item category	Checklist item	Description
Design		Online survey comprising two elements: 1) longitudinal follow-up of the original 2011 MILES study participants, and 2) cross-sectional assessment of a new cohort of participants. All participants were Australian adults with type 1 or type 2 diabetes aged 18-75. The longitudinal cohort were contacted directly be researchers (with their prior consent) to be invited to take part. Participants for the new cohort element were randomly sampled (with stratification by diabetes type and treatment, and state of residence) from the National Diabetes Services Scheme (NDSS). The study was also advertised nationally to supplement the NDSS sampling for the new cohort. The longitudinal and new cohort survey versions were near identical. Hard copy surveys were made available, via post, to those who requested it. Participants completing hardcopy surveys were included in the new cohort sample.
Ethics	Ethics approval	The study was approved by the Deakin University Human research Ethics Committee (2011-046).
	Informed consent	The first survey screen was a detailed plain language description of the study that outlined the study aims, procedure, how long the survey would take, how data would be stored, and what would be done with their information. Participants indicated informed consent by ticking a box. Only after providing informed consent did the participant have access to the survey proper.
	Data protection	Secure survey software and secure, password-protected Deakin University servers were used to ensure data were protected. The dataset has been de-identified, with all possible identifying information stored separately to the data file.
Development and pre-testing		The survey content was informed by the original 2011 MILES survey. Where modifications were made, these decisions were based on thorough review of the literature and discussion with the research team until consensus was reached. The technical functionality and flow of the survey was extensively tested by the research team prior to finalisation.
Recruitment process	Open vs closed survey	The longitudinal element of the study was closed. The new cohort element of the study was open.
	Contact mode	Participants from the original 2011 MILES survey who had consented to be contacted were mailed/emailed a study invitation by the researchers with a unique log-in code to the online survey that was used to match their data with the previous survey data. Participants in the new cohort who

		were sampled through the NDSS received a letter of invitation in the mail directly from the NDSS. Participants in the new cohort who saw the study advertised elsewhere were provided with the study URL so they could enter the survey directly.
	Advertising the survey	The survey was advertised in various diabetes-related print, electronic and social media. Participants who responded to the study from these advertisements entered the new cohort.
Survey administration	Web/email	This was a web-based survey, hosted by Qualtrics™. Participants accessed the survey by first visiting the Diabetes MILES Study website, and then clicking a button to open up the Qualtrics™-hosted survey.
	Context	To access the survey, participants were first directed to a website dedicated to providing information about the Diabetes MILES Study (www.diabetesMILES.org). From this website, they would click a button to open up the Qualtrics™-hosted survey.
	Mandatory/voluntary	Participation was voluntary, and this was outlined to participants during the informed consent process.
	Incentives	Participants were entered into a prize draw to win one of three iPad minis™.
	Time/date	Data were collected between March – May 2015.
	Item randomisation	Not used.
	Adaptive questioning	Branching was used to tailored the survey to diabetes type and treatment, and also to follow up with further questioning conditional to prior responses. For example, participants were first asked if they had ever experienced a hypoglycaemic episode. If they answered yes, a series of additional questions were presented about their experiences of a hypoglycaemic episode(s).
	Number of items	The number of items per page varied between 1 – 48 (with multiple items presented in one table with response required on the same Likert scale).
	Number of screens	Varied widely according to eligibility, survey version and branching.
	Completeness check	Items requiring input for the purposes of tailoring the survey to diabetes type and treatment were mandatory. All other items were optional, but if a participant skipped a question, it was highlighted to them before they moved to the next screen. They could then choose to leave the response blank, or return to the skipped question to provide a response.
	Review step	Participants could not review or change their responses once they moved on to the next screen.

Response rates	Unique site visitor	Unique visitors were determined by IP address, and double-checking identified duplicates were true duplicates on the basis of their demographic information.
	View rate	Necessary detail for calculation was not recorded.
	Participation rate	The response rate to invitations for the new cohort was 8%. The response rate for the longitudinal cohort was 26%. However, the necessary detail to calculate participation rate (those who started the survey versus those who opted out prior to opening the Qualtrics^{TM} site and/or providing informed consent was not recorded.
	Completion rate	0.88 (88%)
Preventing multiple entries from same individual	Cookies used	No.
	IP check	Yes.
	Log file analysis	Not used.
	Registration	Only for the longitudinal cohort participants. They entered a unique code that was used to match their survey responses with their prior data.
Analysis	Handling of incomplete questionnaires	Participant data was used regardless of whether they completed the full survey. For validated scales, small amounts of missing data were tolerated (based on a priori decisions which varied by scale), with expectation-maximisation imputation being used to facilitate calculation of total scores. Participants who had more missing data on a scale than was tolerated were not given a total score for that scale.
	Questionnaires with atypical timestamp	No atypical timestamps were detected.
	Statistical correction	None required.

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Cohort profiles of the cross-sectional and prospective participant groups in the second Diabetes MILES - Australia (MILES-2) study

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Cohort profiles of the cross-sectional and prospective participant groups in the second Diabetes MILES - Australia (MILES-2) study

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ABSTRACT

Purpose: More research into the psychosocial aspects of diabetes is needed so that the health and quality of life of people with the condition can be improved. To fill this gap, we conducted the second Diabetes MILES – Australia study (MILES-2); a survey focused on psychological, behavioural and social aspects of diabetes. The aim of the MILES-2 study was to provide a) longitudinal follow-up of the original MILES 2011 study cohort; b) cross-sectional assessment of a new cohort.

Participants: Eligible participants were English-speaking Australians with type 1 or type 2 diabetes, aged 18-75. Longitudinal cohort participants were mailed / emailed study invitations directly by researchers. Random sampling (stratified by diabetes type, insulin use, state) of the National Diabetes Services Scheme (NDSS) database and nationwide advertisements were used to recruit new cohort participants. The final sample included N=2,342 eligible respondents (longitudinal cohort: n=504; 2015 new cohort: n=1,838); 54% had type 2 diabetes.

Findings to date: Survey respondents were from an advantaged socioeconomic background compared to the general population. Respondents with type 1 diabetes were over-represented in the new cohort (45%) relative to the planned stratification (40% type 1 diabetes, 60% type 2 diabetes). Respondents with insulin-treated type 2 diabetes were under-represented in the new cohort relative to the stratified sampling (42% invited versus 50% response). Participants who completed both the 2011 and 2015 surveys were more likely than those completing the 2011 survey only to have type 1 diabetes, report a higher education and annual income, and live in metropolitan areas. Participant feedback indicated the survey was perceived as relevant and valuable.

Future plans: The depth and breadth of the data available in this large sample will highlight unmet needs and priority areas for future investigation, and crucially, will inform policy, program and intervention development and evaluation in Australia.

Registration: Not applicable.

STRENGTHS AND LIMITATIONS

Strengths

- Key strengths of MILES-2 are the breadth and depth of quantitative data and the large, population-based sample size, which provides sufficient power for various statistical analyses.
- The emerging longitudinal dataset enables investigation of predictors and consequences of psychological distress and sub-optimal self-management, for the first time, in a non-clinical, population-based sample.

Limitations

- The response rates for both the longitudinal (26%) and the new cohorts (8%) in the MILES-2 survey were low.
- In the longitudinal cohort, substantial attrition was evident between the 2011 and 2015 surveys.
- Participants were from a relatively advantaged background, which may result in the under-estimation of social and emotional problems, and problems of healthcare access.

INTRODUCTION

Diabetes is one of the most challenging public health issues faced today. The number of people with diabetes has doubled globally in recent decades[1], and it is predicted that by 2040, 642 million people will have diabetes[2]. Australia is no exception to the global trend, where diabetes is the fastest growing chronic condition, and type 2 diabetes expected to be the largest health burden by 2023[3]. While the majority of Australians with diabetes have type 2 diabetes, the prevalence of both type 1 and type 2 diabetes is increasing[4].

There have been many developments in recent years to improve the management of diabetes: medications (e.g. insulin analogs, GLP-1 agonists, and sodium-glucose co-transporter 2 (SGLT2) inhibitors), technologies (e.g. wearable glucose monitoring devices, 'artificial pancreas', smartphone apps to support self-management), education (e.g. structured group training programs, online self-directed interventions) and healthcare access (e.g. multidisciplinary single-site care, subsidies for devices and consumables). Despite this, many people with diabetes still experience the condition as burdensome and unrelenting[5]. Achieving recommended treatment targets remains a significant challenge for many people with diabetes. Data from the National Health and Nutrition Examination Surveys (NHANES) in the USA indicate that less than 20% of people with diabetes have in-target HbA1c, blood pressure and cholesterol[6], and that this proportion of people meeting the recommended treatment goals has improved only slightly over time[7]. Australian data from 2013-2014 indicate that less than 50% of people with diabetes in primary care are meeting glycaemic targets, and only 20% are meeting all glycaemic and cardiovascular outcome targets[8]. In addition, severe hypoglycaemia remains all too common, with around 20% of adults with diabetes reporting severe hypoglycaemia in the past 3-6 months[9-11]. Systematic reviews demonstrate that psychological problems are prevalent[12-16], including clinically significant depressive symptoms (reported by 8-29% of adults with diabetes; though concerns about over-diagnosis have been raised[17])[12, 13, 18, 19], anxiety (among 7-14%) [14, 19, 20] and diabetes distress (among 18-39%)[19, 21, 22].

Impaired psychological well-being is not only associated with poorer quality of life, but also with less optimal self-care behaviours, hyperglycaemia, a higher risk of developing micro- and macrovascular complications of diabetes, and higher mortality rates[23-26]. This suggests that more research into the behavioural and psychological aspects of diabetes is needed to generate further insights into how both health and quality of life outcomes can be improved. Indeed, there have recently been calls for the prioritisation of research that seeks to understand and address the psychological well-being of people with diabetes[27, 28].

In 2011, we conducted the Diabetes MILES (Management and Impact for Long-term Empowerment and Success) – Australia study[29]. The aim of this national survey of Australian adults living with type 1 or type 2 diabetes was to assess the psychosocial aspects of living with diabetes. The 2011 survey was funded primarily by the National Diabetes Services Scheme (NDSS), an initiative of the Australian Government administered with the assistance of Diabetes Australia. The NDSS provides subsidised products, information and support services for Australians with diabetes, and funds strategic initiatives that align with national priorities. Most Australians diagnosed with diabetes are registered with the scheme, and most participants from the first Diabetes MILES – Australia study were recruited from the NDSS registrant database.

Diabetes MILES – Australia represented a major achievement in the study of diabetes in Australia, as it was the first time that the psychological health, behavioural diabetes management, social impacts, and unmet needs of a large and diverse national sample were assessed, providing a baseline against which the results of future studies can be compared.

The findings of the 2011 Diabetes MILES – Australia study have been disseminated widely in journal articles, at national and international conferences, at health professional training days and community seminars. Publications have addressed a diverse range of topics including psychological insulin resistance amongst adults with type 2 diabetes[30-32]; subjective well-being[33] and suicidal ideation[34] amongst adults with type 1 or type 2 diabetes; measurement of diabetes distress[35]; the relationships between healthcare access and self-management and self-efficacy[36], economic hardship[37], and rural/regional living[38]; and the challenges faced by specific groups such as young adults with type 2 diabetes[39] and severely obese adults with type 2 diabetes[40-42]. Collectively, the findings from the 2011 Diabetes MILES – Australia survey have provided crucial evidence to inform policy, practice and service delivery for adults with type 1 and type 2 diabetes in Australia. For example, the 2011 Diabetes MILES – Australia survey indicated that emotional distress is common amongst Australian adults with diabetes, and subjective well-being is lower in this group than in the general Australian population[33-35, 43]. In response to this evidence, the NDSS initiated the Diabetes and Mental Health National Development Programme, which was led by JS with contributions from CH, JB and AV. This Programme constituted a multi-pronged approach to further understanding the psychological needs of adults with diabetes, and developing resources (e.g. the Diabetes and Emotional Health Handbook[44], and related leaflets for people with diabetes) to aid diabetes health professionals to integrate into routine care psychologically-sensitive practices (e.g. being alert to and identifying, assessing, and addressing diabetes distress). Further, using the 2011 survey evidence about the impaired well-being of Australians with diabetes, CH and JS consulted to the 2016-2018 revision of the Royal Australian College of General Practitioners Guidelines for General Practice Management of Type 2 Diabetes, which consequently includes a recommendation to screen adults with type 2 diabetes for diabetes distress and depressive symptoms annually. Another key finding from the 2011 survey was that negative insulin appraisals amongst adults with type 2 diabetes can persist beyond insulin initiation, and that these negative appraisals were associated with impaired emotional well-being[31]. This result highlighted the need for ongoing assessment of attitudes towards insulin, and holistic, continuing support for this group. In response, the research team is currently working with diabetes organisations (e.g. Diabetes Victoria) to develop plans for further support, education and intervention for adults with type 2 diabetes using insulin.

The Diabetes MILES Study is now an international collaborative, with a similar survey having been conducted in The Netherlands[45]. Diabetes MILES-Youth, a national survey of Australian adolescents with diabetes (aged 12-18 years) and their parents, was conducted in 2014[46].

While the 2011 Diabetes MILES – Australia study provided a valuable 'snapshot', this cross-sectional survey does not allow assessment of change over time, or associations between exposure to a new condition (e.g. commencement of insulin therapy) and key outcomes (e.g. emotional well-being and treatment self-efficacy). Diabetes treatments, programs and services are continually developing and advancing[47], and ongoing survey research at a national level will enable us to track psychosocial well-being and self-management behaviour in parallel with these changes. Further, as psychosocial research in diabetes gains traction and the field

expands, new avenues of investigation have been identified and novel topics of interest have emerged. Examples include stigmatisation of, and discrimination against, people with diabetes[5, 48, 49], memory and cognition[50], and self-compassion[51]. To date, there is little to no population-based data on these important topics in relation to diabetes.

To fill these gaps, we conducted the second Diabetes MILES – Australia (MILES-2) study. In this paper, we detail the methods and cohort profiles of the MILES-2 survey participants. This study had two elements, each with different aims:

1. longitudinal cohort: a follow-up survey of the 2011 Diabetes MILES – Australia participants to allow assessment of change over time in, and prospective investigation of, key psychological and behavioural outcomes. The longitudinal data will enable exploration of key topics, such as:
    a. potential impact of changes in treatment (e.g. initiation of insulin therapy) and/or self-care regimen (e.g. changes in glucose monitoring behaviours) on diabetes-specific distress;
    b. the psychological (e.g. illness beliefs, anxiety, depression) and behavioural (e.g. healthcare visits, diabetes self-care) antecedents of diabetes complications (e.g. diabetic retinopathy);
    c. prospective predictors of the development of psychological problems (e.g. depressive or anxiety symptoms) or diabetes complications.

2. 2015 new cohort: a cross-sectional survey of a new national sample of adults with type 1 or type 2 diabetes to introduce novel, emerging topics of investigation. These new cross-sectional data will enable exploration of novel topics, such as:
    a. perceived and experienced diabetes stigma and weight stigma, and their associations with key psychological problems (e.g. depressive symptoms) and behavioural issues (e.g. medication-taking and blood glucose monitoring);
    b. the relationship between prospective memory (i.e. remembering to perform a planned action) and diabetes self-care behaviours;
    c. the relationship between self-compassion and the experienced emotional burden of diabetes (e.g. diabetes-specific distress).

The reasons for the four-year intervening period between the first and second MILES surveys were both academic and pragmatic. First, an a priori decision was taken in 2011 to follow up the initial cohort of participants within five years (pending funding, which became available in early 2015); and 2011 participants who agreed to join the longitudinal cohort consented expressly to being contacted within this timeframe. Second, as alluded to above, new priority research areas had emerged in the intervening time, and any further lag in collecting new data would have unnecessarily delayed the advancement of knowledge on important topics. Finally, many of the core measures administered to participants in the 2011 and 2015 surveys assess individual-level variables (e.g. depressive symptoms) that can reasonably be expected to change in a period of four years.

COHORT DESCRIPTIONS

Study design and setting

The MILES-2 survey (both for the longitudinal cohort and the 2015 new cohort) was conducted primarily online, although a hard copy version was made available for those who requested it (e.g. due to not having access to, or not knowing how to use, the internet). The study was conducted and is reported according to the Checklist for Reporting Results of Internet E-Survey (CHERRIES, see Appendix 1)[52].

The survey content and procedure used for the longitudinal and new cohorts were near identical. The methods described below refer to both cohorts unless specified otherwise.

Ethics approval and consent

Ethics approval was granted by the Deakin University Human Research Ethics Committee (reference number: 2011-046). All participants provided informed consent, having read a plain language description of the study, using a tick-box form (electronic or in hard copy).

Participant eligibility and recruitment

Eligible participants were adults (aged 18-75 years) living in Australia who had type 1 or type 2 diabetes, and were proficient in English for the purposes of reading and completing the survey (as it was available in English only). People with other types of diabetes (e.g. gestational, Mature Onset Diabetes of the Young (MODY), Latent Autoimmune Diabetes in Adults (LADA)) were not eligible to take part because the survey content was not tailored to address issues specific to these special groups. Similarly, people under the age of 18 and over the age of 75 were not eligible for participation because the survey content and format were likely to be inappropriate for these groups; and, in the case of those under 18 years, so as not to duplicate the efforts of the recent Diabetes MILES Youth survey[46].

Longitudinal cohort recruitment

Of the 3,833 respondents to the 2011 Diabetes MILES – Australia survey, 2,153 (56%) consented to being invited to take part in future longitudinal cohort studies and provided complete email or postal addresses to facilitate contact. Invitations were sent by email where possible (n=1,643), with postal invitations sent initially to only 510 participants who did not provide an email address. An additional 338 invitations were sent by post after email bounce-backs were received. Overall, 88 participants were not contactable by email or post (invitation returned to sender). Thus, 2,065 participants of the 2011 survey received an invitation to take part in the MILES-2 survey; a single reminder email/letter was sent three weeks later.

2015 new cohort recruitment

As in the 2011 survey, the NDSS registrant database was used to contact potential participants. Of the 1.2 million NDSS registrants[53], approximately 47% have indicated consent to be contacted about research participation opportunities. Of these, a stratified random sample of 20,000 registrants were sent a postal invitation directly by the NDSS (i.e. researchers did not have access to the database), which directed them to the online survey website and provided researcher contact details. The sample was stratified according to population in each Australian state, and as follows:

- 8,000 with type 1 diabetes (40% of the total sample)

- 12,000 with type 2 diabetes (60% of the total sample); 6,000 of whom registered as using insulin (50% of type 2 diabetes sample)

Adults with type 1 diabetes and with type 2 diabetes using insulin were purposefully over-sampled to ensure adequate representation of these sub-samples. The sample was not stratified by gender.

To ensure the sample was indeed a new cohort of participants, registrants who were randomly sampled during recruitment for the 2011 Diabetes MILES – Australia survey were excluded from the 2015 sampling. Finally, the study was also advertised nationwide in diabetes-related media (e.g. magazines, e-newsletters, social media).

Data collection and handling procedure

Potential participants were directed to the study website[54] which presented a plain language description of the study and an online consent form. Those who provided informed consent were directed through to the eligibility screening. Ineligible participants were screened out automatically and presented with a message thanking them for their interest and advising they were not eligible to take part. Eligible participants were directed through to the survey proper. At the end of the survey, all respondents were invited to provide their email address to facilitate one or more of the following: 1) entry into a prize draw (chance to win one of three iPad minis™), 2) to receive a free electronic copy of the study report, 3) to receive notifications about future research opportunities, 4) to withdraw data at a later date. Provision of an email address was voluntary, and participants could select to which of the four options they consented.

The MILES-2 survey was hosted by Qualtrics™, a secure, online survey platform. The survey was open for participation for seven weeks (23 March – 11 May 2015). As participants progressed through the survey, their data were saved automatically by Qualtrics™.

All online survey responses (complete and incomplete) were logged by the Qualtrics™ survey platform and downloaded at survey close into data files for analysis in Statistical Package for the Social Sciences (SPSS) (IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp). Hard copy survey responses were entered manually into the SPSS data file by one researcher, and checked for accuracy by a second researcher. Contact details were extracted from the main data file and stored separately in a password-protected folder. Longitudinal cohort participants' 2015 data were matched with their existing 2011 data using the unique log-in code provided, and by validating the match against diabetes type, age and gender.

A total of 2,651 survey responses were recorded by Qualtrics™. However, 148 duplicate cases were identified in the data file (using a combination of IP address and demographic/clinical data such as age, gender, postcode, and diabetes type) and deleted. The main reasons for duplicate cases were:

a) participants who were screened out at the eligibility assessment phase restarted the survey to answer the screening questions in a different way (e.g. changing diabetes type response from 'MODY' to 'type 2 diabetes'), allowing them to unlock the full survey. In these instances, their second attempt was deleted and their data were not included in any analysis due to ineligibility.

b) participants who lost their internet connection or their responses failed to save, and they restarted the survey in order to complete it. In these instances, the most complete entry was retained and the other deleted. If there was no difference in the amount of data available in each case, the first entry was retained.

Response rate

A total of 2,503 unique consenting responses (27 hard copy completions) to the MILES-2 survey were identified, including 2015 new cohort (n=1,970) and longitudinal cohort (n=533) respondents. The response rates for these separate sub-samples are discussed separately below.

The **2015 new cohort** participants who passed the eligibility screening (n=1,829, 93%) had the opportunity to indicate how they heard about the survey. Seventy-nine per cent (n=1,453) of this subsample indicated that they received a letter from the NDSS inviting them to take part, indicating a response rate of 7% of the 20,000 NDSS registrants who received an invitation. Extrapolating this rate to also include those screened out due to ineligibility, the estimated total response rate to the NDSS mail-out is 8%.

Of the 2,065 participants of the original 2011 survey, who indicated willingness to be contacted about similar studies in the future, 533 (26%) participated, and are referred to hereafter as the **longitudinal cohort**. Reasons for non-participation are not known.

Final eligible samples and their characteristics

Of the 2,503 unique respondents, 161 were screened out due to ineligibility. The final cross-sectional sample included N=2,342 eligible participants, comprising n=1,838 2015 new cohort participants and n=504 longitudinal cohort participants. Full sample characteristics are presented in Table 1.

In the final sample, 46% had type 1 diabetes and 54% had type 2 diabetes. Overall, men and women were represented equally (50% versus 50%). Unsurprisingly, participants with type 2 diabetes were substantially older than participants with type 1 diabetes (mean difference: 17 years), but reported shorter diabetes duration (mean difference: 8 years). Amongst those with type 1 diabetes, 35% were managing their diabetes with an insulin pump. Amongst those with type 2 diabetes, 42% were using insulin. Most respondents spoke English as their main language (97%), were married or in a de facto relationship (68%), had vocational or university qualifications (66%), lived in metropolitan areas (61%), were in paid employment (54%), and had an annual household income of more than AU$40,000 per annum (54%).

Tight confidence intervals of 2.02 were evident (calculated using a worst-case scenario proportion of 50%, a 95% confidence level, and sample size of 2,342), providing evidence of sample adequacy.

Table 1: Sample characteristics for the 2015 Diabetes MILES – Australia survey, by diabetes type*

	Type 1 diabetes n=1,078 (46)	**Type 2 diabetes** n=1,264 (54)	**Total sample** N=2,342 (100)
Gender - female	639 (59)	539 (43)	1178 (50)

Age - years	44±15 (18-75)	61±9 (22-75)	53±15 (18-75)
Diabetes duration - years	19±14 (0-68)	11±7 (0-44)	15±12 (0-68)
Primary diabetes management			
Insulin pump therapy	380 (35)	2 (0.2)	382 (16)
Insulin injections	698 (65)	529 (42)	1227 (52)
Non-insulin injectables	-	47 (4)	47 (2)
Blood glucose lowering tablets	-	510 (40)	510 (22)
Diet and/or exercise alone	-	176 (14)	176 (8)
Aboriginal or Torres Strait Islander	14 (1)	22 (2)	36 (2)
Main language spoken at home - English	1054 (98)	1214 (96)	2268 (97)
Country of birth - Australia	831 (77)	889 (70)	1720 (73)
Relationship status			
Single	241 (22)	111 (9)	352 (15)
In a steady relationship	52 (5)	21 (2)	73 (3)
Married or De-Facto	706 (66)	891 (71)	1597 (68)
Separated	18 (2)	36 (3)	54 (2)
Divorced	48 (4)	130 (10)	178 (8)
Widowed	8 (1)	71 (6)	79 (3)
Education			
No qualifications	30 (3)	125 (10)	155 (7)
School/Intermediate certificate	105 (10)	205 (16)	310 (13)
High School/Leaving certificate	181 (17)	140 (11)	321 (14)
Trade training or diploma(s)	252 (23)	382 (30)	634 (27)
University undergraduate degree	269 (25)	223 (18)	492 (21)
Higher university degree	236 (22)	185 (15)	421 (18)
(Un)Employment details			
Paid employment	770 (72)	477 (38)	1247 (54)
Retired	146 (14)	579 (46)	725 (31)
Full-time student	26 (2)	8 (1)	34 (2)
Unpaid household duties	40 (4)	49 (4)	69 (3)
Unemployed	86 (8)	146 (12)	232 (10)
Other	8 (1)	4 (0.3)	12 (1)
Annual household income ($AUD)			
≤20,000	130 (12)	225 (18)	355 (15)
20,001 – 40,000	123 (12)	281 (23)	404 (17)
40,001 – 60,000	135 (13)	199 (16)	334 (14)
60,001 – 100,000	240 (23)	175 (14)	415 (18)
100,001 – 150,000	158 (15)	113 (9)	271 (12)
>150,000	123 (12)	75 (6)	198 (9)
Don't know / prefer not to say	155 (15)	177 (14)	332 (14)
State			
Australian Capital Territory	54 (5)	132 (10)	186 (8)
New South Wales	345 (32)	258 (20)	603 (26)
Northern Territory	9 (0.8)	41 (3)	50 (2)
Queensland	140 (13)	143 (11)	283 (12)
South Australia	86 (8)	120 (10)	206 (9)
Tasmania	50 (5)	120 (10)	170 (7)
Victoria	281 (26)	297(24)	578 (25)
Western Australia	113 (10)	151 (12)	264 (11)
Geographical location			
Metropolitan	483 (63)	750 (60)	1433 (61)

Regional	272 (25)	303 (24)	575 (25)
Rural	122 (11)	206 (16)	328 (14)

Data are n (%) or mean±SD (range)

* Total N reported is not always consistent with total sample size due to missing data for some variables. Percentages do not always sum to 100 due to rounding.

Table 2 compares the sample characteristics of the longitudinal and 2015 new cohorts. With few exceptions, the longitudinal and new cohorts were equivalent on key socio-demographic and clinical characteristics, indicating that the cohorts may be pooled for future analyses. On average, participants with type 1 diabetes in the longitudinal cohort were older and had a longer diabetes duration than the new cohort, but while the difference was significant, it was not notable (<5 year mean difference in both instances). Respondents with type 1 diabetes in the longitudinal cohort were more likely to be using an insulin pump than those in the new cohort. Regardless of diabetes type, compared with the new cohort, the longitudinal cohort was more likely to have a university education, less likely to have no qualifications, and more likely to reside in the state of Victoria.

Table 2: Sample characteristics by cohort*

	Longitudinal Cohort	**2015 new Cohort**	**Sig**
Total eligible sample	**504 (22)#**	**1838 (79)**	
Gender – female	261 (52)	917 (50)	ns
Diabetes type			ns
Type 1 diabetes	236 (47)	842 (46)	
Type 2 diabetes	268 (53)	996 (54)	
Age – years			
Type 1 diabetes	47±14	43±16	<.001
Type 2 diabetes	62±8	61±10	ns
Diabetes duration – years			
Type 1 diabetes	22±14	18±14	<.001
Type 2 diabetes	12±7	11±8	ns
Primary treatment for type 1 diabetes			<.001
Insulin pump therapy	106 (45)	274 (33)	
Insulin injections	130 (55)	568 (67)	
Primary treatment for type 2 diabetes			ns
Insulin pump therapy	0 (0)	2 (0.2)	
Insulin injections	95 (35)	434 (44)	
Non-insulin injectables	11 (4)	36 (4)	
Blood glucose lowering tablets	119 (44)	391 (39)	
Diet and/or exercise alone	43 (16)	133 (13)	
Aboriginal or Torres Strait Islander origin	5 (1)	31 (2)	ns
Main language spoken at home - English	494 (98)	1774 (97)	ns
Country of birth – Australia	387 (77)	1333 (73)	ns
Relationship status			ns
Single	64 (13)	288 (16)	
In a steady relationship	12 (2)	61 (3)	
Married or De-Facto	356 (71)	1241 (68)	
Separated	12 (2)	42 (2)	
Divorced	44 (9)	134 (7)	
Widowed	15 (3)	64 (3)	

Education			
No qualifications	15 (3)	140 (8)	<.001
School/Intermediate certificate	68 (14)	242 (13)	
High School/Leaving certificate	58 (12)	263 (14)	
Trade training or diploma(s)	132 (26)	502 (28)	
University undergraduate degree	123 (25)	369 (20)	
Higher university degree	106 (21)	315 (17)	
(Un)Employment details			
Paid employment	280 (56)	967 (53)	ns
Retired	155 (31)	570 (31)	
Full-time student	6 (1)	28 (2)	
Unpaid household duties	26 (5)	63 (3)	
Unemployed	35 (7)	197 (11)	
Other	2 (0.4)	10 (1)	
Annual household income ($)			
≤20,000	67 (13)	288 (16)	ns
20,001 – 40,000	79 (16)	325 (18)	
40,001 – 60,000	80 (16)	254 (14)	
60,001 – 100,000	94 (19)	321 (18)	
100,001 – 150,000	61 (12)	210 (12)	
>150,000	57 (11)	141 (8)	
Don't know / prefer not to say	65 (13)	267 (15)	
State			
Australian Capital Territory	17 (3)	169 (9)	<.001
New South Wales	105 (21)	498 (27)	
Northern Territory	1 (0.2)	49 (3)	
Queensland	81 (16)	202 (11)	
South Australia	25 (5)	181 (10)	
Tasmania	12 (2)	158 (9)	
Victoria	215 (43)	363 (20)	
Western Australia	47 (9)	217 (12)	
Geographical location			
Metropolitan	312 (63)	1121 (61)	ns
Regional	127 (25)	448 (24)	
Rural	63 (13)	265 (14)	

Data are n (%) or mean±SD (range)

*Table refers only to eligible participants. Total N reported is not always consistent with total sample size due to missing data on some items. Percentages do not always sum to 100 due to rounding.

#Of the 504 longitudinal cohort participants, 459 could be matched with 2011 data.

Depth and breadth of available data

Consistent with the aims of the Diabetes MILES Study initiative, the data available primarily relate to the psychological (e.g. emotional well-being), behavioural (e.g. self-management) and social (e.g. diabetes stigma) aspects of living with diabetes. These data make possible the assessment of prevalence, relationships between key variables, and (in the longitudinal cohort), change over time and associations between exposure to a new condition and key outcomes. The survey included validated scales, study-specific individual items and newly developed measures (for validation). For 'core' constructs (e.g. general and diabetes-specific emotional well-being), the measures used in 2011 were included in the 2015 survey. This was important in order to generate a longitudinal data set for assessing within-group change over time, but also to enable comparison on key issues of the full 2011 and 2015 study samples as representative 'snapshots' of the Australian population of adults with diabetes.

While the 2011 and 2015 surveys had similar content, they were not identical. Some measures (e.g. Resources and Support for diabetes Self Management questionnaire) were not repeated in 2015 because ongoing data collection on the topic was not considered a key priority. Some measures were replaced with another measure of the same construct (e.g. the Diabetes Self-Care Inventory – Revised was replaced with the Summary of Diabetes Self-Care Activities[55]). Some measures were replaced with a shorter version to reduce respondent burden (e.g. the Quality of Life Questionnaire was replaced with the DAWN Impact of Diabetes Profile[5]). Finally, some measures were replaced with measures tailored to diabetes type and/or treatment (e.g. the Diabetes Empowerment Scale Short-Form[56] was replaced with the Confidence in Diabetes Self-care scale, with insulin-using[57] and non-insulin using[58] versions.

In the original (2011) Diabetes MILES study, two alternate survey versions (A and B) were used. To ensure that all longitudinal cohort participants had complete data sets for key variables (e.g. diabetes-specific distress), their 2015 survey content was tailored automatically (based on the unique code they entered) to match the survey version they completed in 2011. However, this automatic tailoring was not possible for those completing the hard copy surveys (n=27), and thus they were treated as new cohort participants.

Survey content was grouped by theme into eight sections: 1) Demographics, 2) My General Well-being, 3) My Feelings about Diabetes, 4) My General Health, 5) Support from Health Professionals, Family and Friends, 6) My Diabetes, 7) My Blood Glucose Levels, 8) My Thoughts and Beliefs. It was also tailored to diabetes type and treatment (based on information provided in the Demographics section of the survey) and as such, not all measures were presented to every participant. Table 3 summarises the topics/constructs, variables and measures used in the 2015 MILES-2 survey (for both the new and longitudinal cohorts separately), and also indicates which of the same content was included in the 2011 survey.

Table 3. Survey content for the 2015 Diabetes MILES – Australia survey

Concept/topic	Measure or variable	2015 new cohort	Longitudinal cohort	2011 survey
Demographics				
Eligibility screen	Diabetes type, age, live in Australia	✓	✓	✓
Demographic & socioeconomic details	Gender, state, postcode, country of birth, language, marital status, living situation, income, employment, education			
Diabetes details	Diabetes duration, diabetes treatment			
Other	Diabetes organisation membership, how they heard about survey			
My General Well-being				
General emotional well-being	World Health Organisation Well-being Index (WHO-5)[59]	✓	✓	✓
	General life satisfaction (single item)[60]			
Depressive symptoms	Patient Health Questionnaire (PHQ-8)[61]			
Anxiety symptoms	Generalised Anxiety Disorder scale (GAD-7)[62]			
My Feelings About Diabetes				
Diabetes-specific distress	Problem Areas In Diabetes Scale (PAID)[63]	✓	✓*	✓*
	Diabetes Distress Scale (DDS)[64]		✓^	✓^
	Type 1 Diabetes Distress Scale (T1-DDS)[65]		✓^#	

Diabetes-related and generic stigma	Type 1 and Type 2 Diabetes Stigma Assessment Scales (DSAS-1[66]; DSAS-2[67])	✓	✓*	
	Stigma Scale for Chronic Illnesses – 8 item version (SSCI-8)[68]	✓	✓*	
	6 study-specific items about portrayal of diabetes in the media	✓	✓	
Quality of life	DAWN Impact of Diabetes Profile (DIDP)[5]	✓	✓	
Illness centrality	Centrality Scale[69]	✓	✓	
My General Health				
Health background	Physical and mental health comorbidities and complications, height and weight, smoking status, health insurance and pension	✓	✓	✓
Weight stigma	Weight Self-Stigma Questionnaire (WSSQ)[70]	✓	✓	
Memory	Prospective and Retrospective Memory Questionnaire (PRMQ)[71]	✓	✓	
Support from Health Professionals, Family and Friends				
Healthcare	Access to providers in last 12 months, main provider, group structured education	✓	✓	✓
Social support	Diabetes Support Scale (DSS)[72]	✓	✓	
	Social Support subscale of Diabetes Care Profile (DCP)[73]	✓	✓	
Peer support	Study-specific items	✓	✓	
My Diabetes				
Self-care	Diet and physical activity subscales of the Summary of Diabetes Self-Care Activities (SDSCA)[55]	✓	✓	
	Study-specific items: dietary behaviours	✓	✓	
	Study-specific items: physical activity behaviours	✓	✓	
	Study-specific items: blood glucose monitoring	✓	✓	
	Modified Importance and Burden items (for diet, physical activity, blood glucose monitoring) from the Summary of Diabetes Self-Care Inventory – Revised (unpublished)	✓	✓	
Diabetes treatment	Study-specific items assessing frequency/time of day for injections/bolusing, frequency of forgetting and skipping injections/bolus/medication dose, reasons for forgetting/skipping	✓	✓	
HbA1c	Study-specific items	✓	✓	✓
App use for self-management support	Study-specific items	✓	✓	
Diabetes-specific self-efficacy	Confidence In Diabetes Self-Care (CIDS) (insulin-using[57] and non-insulin-using versions[58])	✓	✓	
Psychological insulin resistance	Insulin Treatment Appraisal Scale (ITAS)[74]	✓~	✓~	✓~
	'Willingness to begin insulin' single item[75]	✓~	✓~	
My Blood Glucose Levels				
Hyperglycaemia	Two items adapted from the Hyperglycaemia Avoidance Scale (HAS)[76]	✓#	✓#	
Hypoglycaemia	Study-specific items (some based on the Hypoglycaemia Awareness	✓	✓	✓

	Questionnaire[77]) to assess frequency, hospitalisation, insulin adjustment in response to hypoglycaemia, impaired awareness of hypoglycaemia			
	Edinburgh Hypoglycaemia Survey (EHS)[78]	✓	✓	
	Gold Score[79]	✓	✓	✓
My Thoughts and Beliefs				
Self-esteem	Rosenberg Self-Esteem Scale (RSE)[80]	✓	✓	
Self-compassion	Self-Compassion Scale Short Form (SCS-SF)[81]	✓	✓	
Other	Free-text box inviting participants to make any other comments	✓	✓	✓

*Participants who completed survey B version in 2011 only. ^Participants who completed survey A version in 2011 only. #Participants with type 1 diabetes only. ~Participants with type 2 diabetes only.

FINDINGS TO DATE

Sample stratification

The success of the stratified sampling approach was assessed by comparing the sub-sample of new cohort respondents who indicated that they received an invitation direct from the NDSS against the planned stratification (described in Methods). Respondents with type 1 diabetes were slightly over-represented in the new cohort (45%) relative to the planned stratification (40% type 1 diabetes, 60% type 2 diabetes). Relative to the planned stratification for state (designed to reflect the proportion of NDSS registrants per state), there was evidence of over-sampling of participants in the Australian Capital Territory (3% invited versus 11% response), New South Wales (21% versus 26%), the Northern Territory (1% versus 3%) and Tasmania (3% versus 10%). Under-sampling of participants was evident in Queensland (19% invited versus 12% response), South Australia (16% versus 11%), Victoria (20% versus 15%), and Western Australia (17% versus 12%). Respondents with insulin-treated type 2 diabetes were under-represented in the new cohort relative to the stratified sampling (42% invited versus 50% response).

Longitudinal cohort data matching

Of the 504 eligible participants who completed the longitudinal cohort survey, 459 (91%) were matched with their original 2011 data. The representativeness of the longitudinal dataset compared to the original 2011 sample can be assessed by comparing the sample characteristics of those who took part in both 2011 and 2015 with those who took part in 2011 only. As shown in Table 4, participants who completed both the 2011 and 2015 surveys were slightly more likely than those completing the 2011 survey only to have type 1 diabetes, report a higher education and annual income, and live in metropolitan regions of Australia. For those with type 1 diabetes, those who participated in both the 2011 and 2015 surveys had a longer mean diabetes duration relative to those who took part in 2011 only. Among those with type 2 diabetes, the reverse was true: participants of both the 2011 and 2015 surveys had a shorter mean diabetes duration compared to those who took part in 2011 only.

Table 4: Baseline characteristics of longitudinal survey completers (2015 and 2011) versus non-completers (2011 only) *

	2011 only (cross-sectional) cohort	2011 & 2015 (longitudinal) cohort	Sig
TOTAL	**2879 (86)**	**459 (14)**	
Gender - female	1538 (54)	240 (53)	ns
Diabetes type			
Type 1 diabetes	1157 (40)	219 (48)	.002
Type 2 diabetes	1722 (60)	240 (52)	
Age - years			
Type 1 diabetes	42±14	43±13	ns
Type 2 diabetes	59±9	57±8	.016
Diabetes duration - years			
Type 1 diabetes	15±13	18±14	.001
Type 2 diabetes	9±7	8±6	.030
Primary treatment for type 1 diabetes			
Insulin pump therapy	246 (21)	79 (36)	<.001
Insulin injections	902 (79)	140 (64)	
Primary treatment for type 2 diabetes			
Insulin pump therapy	8 (0.0)	0 (0)	
Insulin injections	642 (39)	72 (30)	
Non-insulin injectables	15 (1)	7 (3)	.002
Blood glucose lowering tablets	767 (45)	109 (45)	
Diet and/or exercise alone	266 (16)	52 (22)	
Aboriginal or Torres Strait Islander origin	47 (2)	2 (0.0)	.037
Main language spoken at home - English	2759 (97)	446 (98)	ns
Country of birth - Australia	2119 (74)	354 (77)	ns
Relationship Status			
Single	391 (14)	59 (139)	
In a steady relationship	105 (4)	20 (4)	
Married or De-Facto	1945 (69)	325 (71)	ns
Separated	77 (3)	6 (1)	
Divorced	216 (8)	39 (9)	
Widowed	89 (3)	7 (2)	
Education			
No qualifications	254 (9)	12 (3)	
School/Intermediate certificate	308 (11)	34 (8)	
High School/Leaving certificate	552 (20)	79 (18)	<.001
Trade training / certificate/ diploma	848 (31)	135 (30)	
University undergraduate degree	474 (18)	108 (24)	
Higher university degree	271 (10)	81 (18)	
In paid employment	1654 (57)	310 (68)	<.001
Annual household income ($)			
≤20,000	539 (20)	57 (13)	
20,001 – 40,000	500 (19)	59 (13)	
40,001 – 60,000	502 (19)	79 (18)	<.001
60,001 – 100,000	579 (21)	120 (27)	
100,001 – 150,000	346 (13)	81 (18)	
>150,000	228 (8.)	52 (12)	

Geographical location			<.001
Metropolitan	1425 (51)	275 (61)	
Regional	808 (29)	116 (26)	
Rural	587 (21)	63 (14)	

Data are n (%) or mean±SD (range)
*Data from 2011 Diabetes MILES – Australia.

Qualitative findings

The qualitative data provided by participants in the free-text boxes indicated that in general, the survey was highly acceptable to participants. While some participants felt the survey was *"too long"*, others were appreciative for the *"comprehensive"* and *"thoughtful"* nature of this research. For many, it promoted further learning about diabetes, and a chance to reflect on their attitudes to living with diabetes:

> "*Doing this survey makes me realise that I could access support networks/ forums/ health care practitioners more than I actually do"* (woman, 31 years, type 1 diabetes)

Some participants perceived that *"psychological support doesn't exist"* (woman, 25 years, type 1 diabetes) for their diabetes-related concerns, and therefore were pleased that this work was being conducted:

> *"I would like to say thank you for this survey, as it's good to know that there are people concerned with diabetes and the issues we may have"* (man, 67 years, type 2 diabetes)

STRENGTHS AND LIMITATIONS

Strengths

Key strengths of MILES-2 are the breadth and depth of quantitative data and the large, population-based sample size that will afford the necessary statistical power to investigate sub-groups and conduct multivariate analyses. Our confidence interval calculations confirm that this sample size is adequate to facilitate relatively accurate estimations of population-level statistics. While clinical and biomedical research abounds in the field of diabetes, there is a pressing need for an increased research focus on the psychosocial aspects of the condition[27]. MILES-2 contributes to this gap in our knowledge by providing a rich dataset that combines cross-sectional and longitudinal assessment of key topics such as emotional well-being, self-management, and healthcare access, as well as introducing novel topics of investigation such as social stigma, cognition and memory, and self-compassion. The qualitative feedback from participants indicated that the topics included in the survey were relevant to them, and the survey was generally very well received.

The survey was conducted primarily online, with only 27 of the 2,342 respondents (1%) asking to complete a hard copy version. The online survey methods were successful in generating a sample with gender balance, a wide age range, diverse socio-economic backgrounds, and a representative mix of people living in metropolitan, regional, and rural areas in all states and

territories of Australia. The online survey was a successful and economical approach to surveying a wide range of Australian adults with diabetes, all within a relatively short time period (seven weeks).

The significance of the emerging longitudinal dataset is particularly noteworthy. For the first time, it will be possible to explore predictors and consequences of psychological distress and sub-optimal behavioural diabetes management in a non-clinical, population-based sample. It represents the first attempt to track the natural trajectory of emotional problems in people with diabetes (e.g. diabetes distress) and to investigate any social, economic, and/or demographic factors that may contribute to variation in psychological experiences. This in turn will enable better tailoring of interventions to meet those with greatest need. It is our intention to conduct further surveys in the future to continue to follow all respondents who have indicated willingness to continue their participation. This will enable us to build on the existing longitudinal dataset using a third wave of data collection, and to increase the sample size and breadth of survey topics available in the longitudinal cohort.

Limitations

Response rates

The response rates for both the longitudinal and the new cohorts in the MILES-2 survey were low; the longitudinal cohort had a markedly better response rate (26%) than the 2015 new cohort (8%). It is possible that respondents who agreed to take part in future surveys in 2011 had a higher level of commitment to and interest in the Diabetes MILES Study due to their previous participation.

In the longitudinal cohort, substantial attrition was evident between the 2011 and 2015 surveys, and the response rate is notably lower than other health-related longitudinal Australian surveys[82, 83]. However, these other initiatives were very well resourced, enabling many repeat attempts at contact using various methods. For MILES-2, only two contacts were possible (invitation plus one reminder). Further, MILES-2 focused specifically on adults with type 1 or type 2 diabetes aged 18-75, whereas in contrast, the other initiatives sampled the general population and did not focus on a particular condition. It has been noted that the population being sampled is the most important determining factor for survey response rates[84], and thus comparison of the MILES-2 response rate with other Australian general population surveys is not necessarily appropriate. People with diabetes are more likely than the general population to have serious physical and mental health comorbidities[12, 13, 85, 86], impaired general well-being[33], and those with type 2 diabetes are more likely to be socioeconomically disadvantaged[87], making non-response and problematic attrition more likely[88, 89].

Another possible explanation for the relatively high rate of attrition between the 2011 and 2015 surveys is the different methods of recruitment and data collection. In 2011, participants received a hard copy survey; online survey completion was possible but 70% of 2011 survey respondents completed the hard copy version. In contrast, the 2015 survey was online by default, and respondents needed to request a hard copy. This may have created too many barriers to participation for some, leading to non-response.

The response rate of the 2015 new cohort is low at 8%, and considerably lower than the 18% observed in the 2011 survey[29]. However, a number of factors may explain this. First, as noted

above, the default online data collection may have been a barrier to participation. Second, the survey took place at a time when NDSS registrants were being contacted frequently for research purposes, which was not the case in 2011. On the advice of the NDSS, the survey launch date was pushed back from November 2014 to March 2015 in an attempt to avoid survey fatigue. However, the low response rate suggests that this delay was insufficient and that NDSS registrants may have been burdened by too many research participation requests. Finally, online surveys are now prolific, and decreasing response rates have been noted elsewhere[84]. Thus, the low response rate observed in the 2015 new cohort of the MILES-2 survey may be reflective of a broader trend, compounded by the challenges faced by this population as already described.

In spite of the low response rates, as noted above, the sample sizes obtained are more than adequate to facilitate inferential data analyses, and to draw conclusions about the unmet needs of Australian adults with type 1 and type 2 diabetes.

Stratification of the new cohort sample

The sampling for the new cohort was stratified by diabetes type, insulin use (type 2 diabetes only), and Australian state of residence. Respondents with type 1 diabetes were slightly over-represented in our sample (45%) relative to the stratification (40%). This may reflect a generally higher level of engagement in diabetes-related activities and advocacy in this group relative to those with type 2 diabetes.

Amongst respondents with type 2 diabetes, 42% were using insulin which is almost double the proportion observed on the NDSS database (24%), but less than anticipated given the purposeful sampling stratification (50%). Based on our previous research, Australian adults with type 2 diabetes who use insulin (compared with those not using insulin) have a longer diabetes duration[90], are more likely to have at least one diabetes-related complication[31, 32], and are more likely to have depressive and anxiety symptoms[43]. These factors may make them less likely to engage in research initiatives[88, 89].

Sample representativeness

The NDSS is considered to be one of the best national sources of data about Australians with diabetes[91], and thus the representativeness of our study sample can best be determined by comparing our sample characteristics with the NDSS registrant database characteristics. Notwithstanding the purposeful stratification and oversampling of adults with type 1 diabetes and those with insulin-treated type 2 diabetes, the gender balance was broadly representative of people registered on the NDSS database[90]. Overall, men and women were represented equally in the sample (50% men; 50% women) and the proportions in our sample approximate the NDSS register (52% men versus 48%).

Amongst those with type 1 diabetes, 35% were using an insulin pump to manage their diabetes. As only 10% of adults with type 1 diabetes registered with the NDSS use an insulin pump [92], it appears that this group is over-represented in our sample. While insulin pump users were intentionally over-sampled in the 2011 survey this was not the case for the 2015 new cohort, and yet they were over-represented in the sample anyway. The over-representation of pump users is consistent with research participation patterns observed in similar studies[44, 45].

Pump users may be more engaged in research because they perceive themselves to benefit from advances in knowledge, or it may be reflective of the fact that pump users tend to be more highly educated and from higher socio-economic backgrounds relative to non-pump users[92].

Compared with the Australian general population, our sample was more likely to speak English as their main language[93], to be married or in a de facto relationship[94], to be in paid employment[95], and have post-high school qualifications[96]. This indicates that those who took part are a relatively privileged sample with significant social resources who are likely to have better health literacy and access to health services than Australians with diabetes generally. This self-selection bias has been observed in many web-based studies[97, 98], and may result in the under-estimation of social and emotional problems, and problems of healthcare access. However, a key focus of future inferential analyses of the MILES-2 data will be the relationships between variables, and the self-selection bias is likely to have minimal impact on this. Weighting of cases may be considered for some future analyses, depending on the sub-sample and outcome variables being used. For future MILES studies, consideration will be given to strategies that will address this under-sampling of participants from less advantaged backgrounds such as community outreach through health professionals and diabetes clinics, collaborating with researchers with expertise in working with Aboriginal and Torres Strait Islander communities, and stronger promotion of the availability of hard copy versions of the survey.

FUTURE DIRECTIONS AND COLLABORATIONS

Subject to funding availability, we plan ongoing follow-up (approximately every four years) of the longitudinal cohort, and we expect to be able to grow both the cohort and the depth and breadth of data available by also conducting follow-up MILES surveys with the 2015 new cohort. To maintain participant engagement and therefore aid retention, we are currently writing a report that summarises top-level findings of the study for a lay audience. All MILES-2 participants were given the opportunity to opt to receive a free electronic copy of the report when it becomes available.

One key direction for future data analysis and publication is examination of within-participant changes between 2011 and 2015 on variables such as depressive and anxiety symptoms, diabetes distress, and insulin appraisals. Additional priority avenues of enquiry will include identifying the psychological and behavioural correlates of diabetes distress, hypoglycaemia avoidance, and depressive symptoms to inform intervention development, exploring associations with diabetes stigma and psychological and behavioural outcomes, characterising the use of technologies (e.g., smartphone apps) to aid self-management, and psychometric analysis of scales that have not previously been used in an Australian context (e.g. DIDP). Findings from MILES-2 will be disseminated through academic publications, conference presentations, health professional training and community symposia over several years.

We encourage collaborations from researchers with relevant expertise in the field. Researchers may gain access to the second Diabetes MILES – Australia survey dataset upon submission of a proposal detailing the topics of interest, key research questions, and hypotheses. Proposals will be evaluated by the Diabetes MILES Study research team on the basis of feasibility, relevance,

novelty, and expertise of the researchers. Enquires should be directed to Dr Jessica Browne (first author).

CONCLUSIONS

The second Diabetes MILES – Australia study builds on the previous Diabetes MILES Study initiatives to deliver Australia's first large-scale longitudinal assessment of the psychosocial aspects of type 1 and type 2 diabetes, and to introduce novel topics of investigation at a population level. The depth and breadth of the data available in this large sample will raise further awareness of the psychosocial impact of living with type 1 and type 2 diabetes, will highlight unmet needs and priority areas for future investigation, and crucially, will inform policy, program and intervention development and evaluation.

FURTHER DETAILS

Ethics approval and consent to participate

This study was approved by the Deakin University Human research Ethics Committee (2011-046). All participants provided informed consent.

Data sharing statement

The second Diabetes MILES – Australia survey dataset is available for analysis by researchers with interest and expertise in this field. For further information, please contact: jbrowne@acbrd.org.au

Competing interests

All authors have completed the ICMJE uniform disclosure at www.icmje.org/coi_disclosure.pdf and declare: financial support for the submitted work from Sanofi ANZ in the form of an unrestricted educational grant; JB has done consultancy work for Sanofi ANZ, has served on a Sanofi ANZ advisory board, and has had travel expenses covered by Sanofi ANZ, with all monies given to her institution. FP has served on an advisory board for Sanofi-Aventis, with monies paid to him personally. JS has done consultancy work for Sanofi ANZ and has had travel expenses covered by Sanofi ANZ, with all monies paid to her institution. EHT, ADV, and CH have no relevant conflicts of interest to declare.

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Author's contributions

JS conceived The Diabetes MILES Study, and together with FP developed The Diabetes MILES Study International Collaborative. All authors contributed to the development of the study design and survey content. JB project managed MILES-2, and wrote the first draft of this manuscript with substantial input from EHT. All authors provided substantial intellectual contributions to the manuscript by providing feedback on drafts. All authors approved the final manuscript.

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Appendix 1. CHERRIES checklist for MILES-2 online survey

Item category	Checklist item	Description
Design		Online survey comprising two elements: 1) longitudinal follow-up of the original 2011 MILES study participants, and 2) cross-sectional assessment of a new cohort of participants. All participants were Australian adults with type 1 or type 2 diabetes aged 18-75. The longitudinal cohort were contacted directly be researchers (with their prior consent) to be invited to take part. Participants for the new cohort element were randomly sampled (with stratification by diabetes type and treatment, and state of residence) from the National Diabetes Services Scheme (NDSS). The study was also advertised nationally to supplement the NDSS sampling for the new cohort. The longitudinal and new cohort survey versions were near identical. Hard copy surveys were made available, via post, to those who requested it. Participants completing hardcopy surveys were included in the new cohort sample.
Ethics	Ethics approval	The study was approved by the Deakin University Human research Ethics Committee (2011-046).
	Informed consent	The first survey screen was a detailed plain language description of the study that outlined the study aims, procedure, how long the survey would take, how data would be stored, and what would be done with their information. Participants indicated informed consent by ticking a box. Only after providing informed consent did the participant have access to the survey proper.
	Data protection	Secure survey software and secure, password-protected Deakin University servers were used to ensure data were protected. The dataset has been de-identified, with all possible identifying information stored separately to the data file.
Development and pre-testing		The survey content was informed by the original 2011 MILES survey. Where modifications were made, these decisions were based on thorough review of the literature and discussion with the research team until consensus was reached. The technical functionality and flow of the survey was extensively tested by the research team prior to finalisation.
Recruitment process	Open vs closed survey	The longitudinal element of the study was closed. The new cohort element of the study was open.
	Contact mode	Participants from the original 2011 MILES survey who had consented to be contacted were mailed/emailed a study invitation by the researchers with a unique log-in code to the online survey that was used to match their data with the previous survey data. Participants in the new cohort who

		were sampled through the NDSS received a letter of invitation in the mail directly from the NDSS. Participants in the new cohort who saw the study advertised elsewhere were provided with the study URL so they could enter the survey directly.
	Advertising the survey	The survey was advertised in various diabetes-related print, electronic and social media. Participants who responded to the study from these advertisements entered the new cohort.
Survey administration	Web/email	This was a web-based survey, hosted by Qualtrics™. Participants accessed the survey by first visiting the Diabetes MILES Study website, and then clicking a button to open up the Qualtrics™-hosted survey.
	Context	To access the survey, participants were first directed to a website dedicated to providing information about the Diabetes MILES Study (www.diabetesMILES.org). From this website, they would click a button to open up the Qualtrics™-hosted survey.
	Mandatory/voluntary	Participation was voluntary, and this was outlined to participants during the informed consent process.
	Incentives	Participants were entered into a prize draw to win one of three iPad minis™.
	Time/date	Data were collected between March – May 2015.
	Item randomisation	Not used.
	Adaptive questioning	Branching was used to tailored the survey to diabetes type and treatment, and also to follow up with further questioning conditional to prior responses. For example, participants were first asked if they had ever experienced a hypoglycaemic episode. If they answered yes, a series of additional questions were presented about their experiences of a hypoglycaemic episode(s).
	Number of items	The number of items per page varied between 1 – 48 (with multiple items presented in one table with response required on the same Likert scale).
	Number of screens	Varied widely according to eligibility, survey version and branching.
	Completeness check	Items requiring input for the purposes of tailoring the survey to diabetes type and treatment were mandatory. All other items were optional, but if a participant skipped a question, it was highlighted to them before they moved to the next screen. They could then choose to leave the response blank, or return to the skipped question to provide a response.
	Review step	Participants could not review or change their responses once they moved on to the next screen.

Response rates	Unique site visitor	Unique visitors were determined by IP address, and double-checking identified duplicates were true duplicates on the basis of their demographic information.
	View rate	Necessary detail for calculation was not recorded.
	Participation rate	The response rate to invitations for the new cohort was 8%. The response rate for the longitudinal cohort was 26%. However, the necessary detail to calculate participation rate (those who started the survey versus those who opted out prior to opening the Qualtrics™ site and/or providing informed consent was not recorded.
	Completion rate	0.88 (88%)
Preventing multiple entries from same individual	Cookies used	No.
	IP check	Yes.
	Log file analysis	Not used.
	Registration	Only for the longitudinal cohort participants. They entered a unique code that was used to match their survey responses with their prior data.
Analysis	Handling of incomplete questionnaires	Participant data was used regardless of whether they completed the full survey. For validated scales, small amounts of missing data were tolerated (based on a priori decisions which varied by scale), with expectation-maximisation imputation being used to facilitate calculation of total scores. Participants who had more missing data on a scale than was tolerated were not given a total score for that scale.
	Questionnaires with atypical timestamp	No atypical timestamps were detected.
	Statistical correction	None required.

BMJ Open

Cohort profiles of the cross-sectional and prospective participant groups in the second Diabetes MILES - Australia (MILES-2) study

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Cohort profiles of the cross-sectional and prospective participant groups in the second Diabetes MILES - Australia (MILES-2) study

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ABSTRACT

Purpose: More research into the psychosocial aspects of diabetes is needed so that the health and quality of life of people with the condition can be improved. To fill this gap, we conducted the second Diabetes MILES – Australia study (MILES-2); a survey focused on psychological, behavioural and social aspects of diabetes. The aim of the MILES-2 study was to provide a) longitudinal follow-up of the original MILES 2011 study cohort; b) cross-sectional assessment of a new cohort.

Participants: Eligible participants were English-speaking Australians with type 1 or type 2 diabetes, aged 18-75. Longitudinal cohort participants were mailed / emailed study invitations directly by researchers. Random sampling (stratified by diabetes type, insulin use, state) of the National Diabetes Services Scheme (NDSS) database and nationwide advertisements were used to recruit new cohort participants. The final sample included N=2,342 eligible respondents (longitudinal cohort: n=504; 2015 new cohort: n=1,838); 54% had type 2 diabetes.

Findings to date: Survey respondents were from an advantaged socioeconomic background compared to the general population. Respondents with type 1 diabetes were over-represented in the new cohort (45%) relative to the planned stratification (40% type 1 diabetes, 60% type 2 diabetes). Respondents with insulin-treated type 2 diabetes were under-represented in the new cohort relative to the stratified sampling (42% invited versus 50% response). Participants who completed both the 2011 and 2015 surveys were more likely than those completing the 2011 survey only to have type 1 diabetes, report a higher education and annual income, and live in metropolitan areas. Participant feedback indicated the survey was perceived as relevant and valuable.

Future plans: The depth and breadth of the data available in this large sample will highlight unmet needs and priority areas for future investigation, and crucially, will inform policy, program and intervention development and evaluation in Australia.

Registration: Not applicable.

STRENGTHS AND LIMITATIONS

Strengths

- Key strengths of MILES-2 are the breadth and depth of quantitative data and the large, population-based sample size, which provides sufficient power for various statistical analyses.
- The emerging longitudinal dataset enables investigation of predictors and consequences of psychological distress and sub-optimal self-management, for the first time, in a non-clinical, population-based sample.

Limitations

- The response rates for both the longitudinal (26%) and the new cohorts (8%) in the MILES-2 survey were low.
- In the longitudinal cohort, substantial attrition was evident between the 2011 and 2015 surveys.
- Participants were from a relatively advantaged background, which may result in the under-estimation of social and emotional problems, and problems of healthcare access.

INTRODUCTION

Diabetes is one of the most challenging public health issues faced today. The number of people with diabetes has doubled globally in recent decades[1], and it is predicted that by 2040, 642 million people will have diabetes[2]. Australia is no exception to the global trend, where diabetes is the fastest growing chronic condition, and type 2 diabetes expected to be the largest health burden by 2023[3]. While the majority of Australians with diabetes have type 2 diabetes, the prevalence of both type 1 and type 2 diabetes is increasing[4].

There have been many developments in recent years to improve the management of diabetes: medications (e.g. insulin analogs, GLP-1 agonists, and sodium-glucose co-transporter 2 (SGLT2) inhibitors), technologies (e.g. wearable glucose monitoring devices, 'artificial pancreas', smartphone apps to support self-management), education (e.g. structured group training programs, online self-directed interventions) and healthcare access (e.g. multidisciplinary single-site care, subsidies for devices and consumables). Despite this, many people with diabetes still experience the condition as burdensome and unrelenting[5]. Achieving recommended treatment targets remains a significant challenge for many people with diabetes. Data from the National Health and Nutrition Examination Surveys (NHANES) in the USA indicate that less than 20% of people with diabetes have in-target HbA1c, blood pressure and cholesterol[6], and that this proportion of people meeting the recommended treatment goals has improved only slightly over time[7]. Australian data from 2013-2014 indicate that less than 50% of people with diabetes in primary care are meeting glycaemic targets, and only 20% are meeting all glycaemic and cardiovascular outcome targets[8]. In addition, severe hypoglycaemia remains all too common, with around 20% of adults with diabetes reporting severe hypoglycaemia in the past 3-6 months[9-11]. Systematic reviews demonstrate that psychological problems are prevalent[12-16], including clinically significant depressive symptoms (reported by 8-29% of adults with diabetes; though concerns about over-diagnosis have been raised[17])[12, 13, 18, 19], anxiety (among 7-14%) [14, 19, 20] and diabetes distress (among 18-39%)[19, 21, 22].

Impaired psychological well-being is not only associated with poorer quality of life, but also with less optimal self-care behaviours, hyperglycaemia, a higher risk of developing micro- and macrovascular complications of diabetes, and higher mortality rates[23-26]. This suggests that more research into the behavioural and psychological aspects of diabetes is needed to generate further insights into how both health and quality of life outcomes can be improved. Indeed, there have recently been calls for the prioritisation of research that seeks to understand and address the psychological well-being of people with diabetes[27, 28].

In 2011, we conducted the Diabetes MILES (Management and Impact for Long-term Empowerment and Success) – Australia study[29]. The aim of this national survey of Australian adults living with type 1 or type 2 diabetes was to assess the psychosocial aspects of living with diabetes. The 2011 survey was funded primarily by the National Diabetes Services Scheme (NDSS), an initiative of the Australian Government administered with the assistance of Diabetes Australia. The NDSS provides subsidised products, information and support services for Australians with diabetes, and funds strategic initiatives that align with national priorities. Most Australians diagnosed with diabetes are registered with the scheme, and most participants from the first Diabetes MILES – Australia study were recruited from the NDSS registrant database.

Diabetes MILES – Australia represented a major achievement in the study of diabetes in Australia, as it was the first time that the psychological health, behavioural diabetes management, social impacts, and unmet needs of a large and diverse national sample were assessed, providing a baseline against which the results of future studies can be compared.

The findings of the 2011 Diabetes MILES – Australia study have been disseminated widely in journal articles, at national and international conferences, at health professional training days and community seminars. Publications have addressed a diverse range of topics including psychological insulin resistance amongst adults with type 2 diabetes[30-32]; subjective well-being[33] and suicidal ideation[34] amongst adults with type 1 or type 2 diabetes; measurement of diabetes distress[35]; the relationships between healthcare access and self-management and self-efficacy[36], economic hardship[37], and rural/regional living[38]; and the challenges faced by specific groups such as young adults with type 2 diabetes[39] and severely obese adults with type 2 diabetes[40-42]. Collectively, the findings from the 2011 Diabetes MILES – Australia survey have provided crucial evidence to inform policy, practice and service delivery for adults with type 1 and type 2 diabetes in Australia. For example, the 2011 Diabetes MILES – Australia survey indicated that emotional distress is common amongst Australian adults with diabetes, and subjective well-being is lower in this group than in the general Australian population[33-35, 43]. In response to this evidence, the NDSS initiated the Diabetes and Mental Health National Development Programme, which was led by JS with contributions from CH, JB and AV. This Programme constituted a multi-pronged approach to further understanding the psychological needs of adults with diabetes, and developing resources (e.g. the Diabetes and Emotional Health Handbook[44], and related leaflets for people with diabetes) to aid diabetes health professionals to integrate into routine care psychologically-sensitive practices (e.g. being alert to and identifying, assessing, and addressing diabetes distress). Further, using the 2011 survey evidence about the impaired well-being of Australians with diabetes, CH and JS consulted to the 2016-2018 revision of the Royal Australian College of General Practitioners Guidelines for General Practice Management of Type 2 Diabetes, which consequently includes a recommendation to screen adults with type 2 diabetes for diabetes distress and depressive symptoms annually. Another key finding from the 2011 survey was that negative insulin appraisals amongst adults with type 2 diabetes can persist beyond insulin initiation, and that these negative appraisals were associated with impaired emotional well-being[31]. This result highlighted the need for ongoing assessment of attitudes towards insulin, and holistic, continuing support for this group. In response, the research team is currently working with diabetes organisations (e.g. Diabetes Victoria) to develop plans for further support, education and intervention for adults with type 2 diabetes using insulin.

The Diabetes MILES Study is now an international collaborative, with a similar survey having been conducted in The Netherlands[45]. Diabetes MILES-Youth, a national survey of Australian adolescents with diabetes (aged 12-18 years) and their parents, was conducted in 2014[46].

While the 2011 Diabetes MILES – Australia study provided a valuable 'snapshot', this cross-sectional survey does not allow assessment of change over time, or associations between exposure to a new condition (e.g. commencement of insulin therapy) and key outcomes (e.g. emotional well-being and treatment self-efficacy). Diabetes treatments, programs and services are continually developing and advancing[47], and ongoing survey research at a national level will enable us to track psychosocial well-being and self-management behaviour in parallel with these changes. Further, as psychosocial research in diabetes gains traction and the field

expands, new avenues of investigation have been identified and novel topics of interest have emerged. Examples include stigmatisation of, and discrimination against, people with diabetes[5, 48, 49], memory and cognition[50], and self-compassion[51]. To date, there is little to no population-based data on these important topics in relation to diabetes.

To fill these gaps, we conducted the second Diabetes MILES – Australia (MILES-2) study. In this paper, we detail the methods and cohort profiles of the MILES-2 survey participants. This study had two elements, each with different aims:

1. longitudinal cohort: a follow-up survey of the 2011 Diabetes MILES – Australia participants to allow assessment of change over time in, and prospective investigation of, key psychological and behavioural outcomes. The longitudinal data will enable exploration of key topics, such as:
    a. potential impact of changes in treatment (e.g. initiation of insulin therapy) and/or self-care regimen (e.g. changes in glucose monitoring behaviours) on diabetes-specific distress;
    b. the psychological (e.g. illness beliefs, anxiety, depression) and behavioural (e.g. healthcare visits, diabetes self-care) antecedents of diabetes complications (e.g. diabetic retinopathy);
    c. prospective predictors of the development of psychological problems (e.g. depressive or anxiety symptoms) or diabetes complications.

2. 2015 new cohort: a cross-sectional survey of a new national sample of adults with type 1 or type 2 diabetes to introduce novel, emerging topics of investigation. These new cross-sectional data will enable exploration of novel topics, such as:
    a. perceived and experienced diabetes stigma and weight stigma, and their associations with key psychological problems (e.g. depressive symptoms) and behavioural issues (e.g. medication-taking and blood glucose monitoring);
    b. the relationship between prospective memory (i.e. remembering to perform a planned action) and diabetes self-care behaviours;
    c. the relationship between self-compassion and the experienced emotional burden of diabetes (e.g. diabetes-specific distress).

The reasons for the four-year intervening period between the first and second MILES surveys were both academic and pragmatic. First, an a priori decision was taken in 2011 to follow up the initial cohort of participants within five years (pending funding, which became available in early 2015); and 2011 participants who agreed to join the longitudinal cohort consented expressly to being contacted within this timeframe. Second, as alluded to above, new priority research areas had emerged in the intervening time, and any further lag in collecting new data would have unnecessarily delayed the advancement of knowledge on important topics. Finally, many of the core measures administered to participants in the 2011 and 2015 surveys assess individual-level variables (e.g. depressive symptoms) that can reasonably be expected to change in a period of four years.

COHORT DESCRIPTIONS

Study design and setting

The MILES-2 survey (both for the longitudinal cohort and the 2015 new cohort) was conducted primarily online, although a hard copy version was made available for those who requested it (e.g. due to not having access to, or not knowing how to use, the internet). The study was conducted and is reported according to the Checklist for Reporting Results of Internet E-Survey (CHERRIES, see Appendix 1)[52].

The survey content and procedure used for the longitudinal and new cohorts were near identical. The methods described below refer to both cohorts unless specified otherwise.

Ethics approval and consent

Ethics approval was granted by the Deakin University Human Research Ethics Committee (reference number: 2011-046). All participants provided informed consent, having read a plain language description of the study, using a tick-box form (electronic or in hard copy).

Participant eligibility and recruitment

Eligible participants were adults (aged 18-75 years) living in Australia who had type 1 or type 2 diabetes, and were proficient in English for the purposes of reading and completing the survey (as it was available in English only). People with other types of diabetes (e.g. gestational, Mature Onset Diabetes of the Young (MODY), Latent Autoimmune Diabetes in Adults (LADA)) were not eligible to take part because the survey content was not tailored to address issues specific to these special groups. Similarly, people under the age of 18 and over the age of 75 were not eligible for participation because the survey content and format were likely to be inappropriate for these groups; and, in the case of those under 18 years, so as not to duplicate the efforts of the recent Diabetes MILES Youth survey[46].

Longitudinal cohort recruitment

Of the 3,833 respondents to the 2011 Diabetes MILES – Australia survey, 2,153 (56%) consented to being invited to take part in future longitudinal cohort studies and provided complete email or postal addresses to facilitate contact. Invitations were sent by email where possible (n=1,643), with postal invitations sent initially to only 510 participants who did not provide an email address. An additional 338 invitations were sent by post after email bounce-backs were received. Overall, 88 participants were not contactable by email or post (invitation returned to sender). Thus, 2,065 participants of the 2011 survey received an invitation to take part in the MILES-2 survey; a single reminder email/letter was sent three weeks later.

2015 new cohort recruitment

As in the 2011 survey, the NDSS registrant database was used to contact potential participants. Of the 1.2 million NDSS registrants[53], approximately 47% have indicated consent to be contacted about research participation opportunities. Of these, a stratified random sample of 20,000 registrants were sent a postal invitation directly by the NDSS (i.e. researchers did not have access to the database), which directed them to the online survey website and provided researcher contact details. The sample was stratified according to population in each Australian state, and as follows:

- 8,000 with type 1 diabetes (40% of the total sample)

- 12,000 with type 2 diabetes (60% of the total sample); 6,000 of whom registered as using insulin (50% of type 2 diabetes sample)

Adults with type 1 diabetes and with type 2 diabetes using insulin were purposefully over-sampled to ensure adequate representation of these sub-samples. The sample was not stratified by gender.

To ensure the sample was indeed a new cohort of participants, registrants who were randomly sampled during recruitment for the 2011 Diabetes MILES – Australia survey were excluded from the 2015 sampling. Finally, the study was also advertised nationwide in diabetes-related media (e.g. magazines, e-newsletters, social media).

Data collection and handling procedure

Potential participants were directed to the study website[54] which presented a plain language description of the study and an online consent form. Those who provided informed consent were directed through to the eligibility screening. Ineligible participants were screened out automatically and presented with a message thanking them for their interest and advising they were not eligible to take part. Eligible participants were directed through to the survey proper. At the end of the survey, all respondents were invited to provide their email address to facilitate one or more of the following: 1) entry into a prize draw (chance to win one of three iPad minis™), 2) to receive a free electronic copy of the study report, 3) to receive notifications about future research opportunities, 4) to withdraw data at a later date. Provision of an email address was voluntary, and participants could select to which of the four options they consented.

The MILES-2 survey was hosted by Qualtrics™, a secure, online survey platform. The survey was open for participation for seven weeks (23 March – 11 May 2015). As participants progressed through the survey, their data were saved automatically by Qualtrics™.

All online survey responses (complete and incomplete) were logged by the Qualtrics™ survey platform and downloaded at survey close into data files for analysis in Statistical Package for the Social Sciences (SPSS) (IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp). Hard copy survey responses were entered manually into the SPSS data file by one researcher, and checked for accuracy by a second researcher. Contact details were extracted from the main data file and stored separately in a password-protected folder. Longitudinal cohort participants' 2015 data were matched with their existing 2011 data using the unique log-in code provided, and by validating the match against diabetes type, age and gender.

A total of 2,651 survey responses were recorded by Qualtrics™. However, 148 duplicate cases were identified in the data file (using a combination of IP address and demographic/clinical data such as age, gender, postcode, and diabetes type) and deleted. The main reasons for duplicate cases were:

a) participants who were screened out at the eligibility assessment phase restarted the survey to answer the screening questions in a different way (e.g. changing diabetes type response from 'MODY' to 'type 2 diabetes'), allowing them to unlock the full survey. In these instances, their second attempt was deleted and their data were not included in any analysis due to ineligibility.

b) participants who lost their internet connection or their responses failed to save, and they restarted the survey in order to complete it. In these instances, the most complete entry was retained and the other deleted. If there was no difference in the amount of data available in each case, the first entry was retained.

Response rate

A total of 2,503 unique consenting responses (27 hard copy completions) to the MILES-2 survey were identified, including 2015 new cohort (n=1,970) and longitudinal cohort (n=533) respondents. The response rates for these separate sub-samples are discussed separately below.

The **2015 new cohort** participants who passed the eligibility screening (n=1,829, 93%) had the opportunity to indicate how they heard about the survey. Seventy-nine per cent (n=1,453) of this subsample indicated that they received a letter from the NDSS inviting them to take part, indicating a response rate of 7% of the 20,000 NDSS registrants who received an invitation. Extrapolating this rate to also include those screened out due to ineligibility, the estimated total response rate to the NDSS mail-out is 8%.

Of the 2,065 participants of the original 2011 survey, who indicated willingness to be contacted about similar studies in the future, 533 (26%) participated, and are referred to hereafter as the **longitudinal cohort**. Reasons for non-participation are not known.

Final eligible samples and their characteristics

Of the 2,503 unique respondents, 161 were screened out due to ineligibility. The final cross-sectional sample included N=2,342 eligible participants, comprising n=1,838 2015 new cohort participants and n=504 longitudinal cohort participants. Full sample characteristics are presented in Table 1.

In the final sample, 46% had type 1 diabetes and 54% had type 2 diabetes. Overall, men and women were represented equally (50% versus 50%). Unsurprisingly, participants with type 2 diabetes were substantially older than participants with type 1 diabetes (mean difference: 17 years), but reported shorter diabetes duration (mean difference: 8 years). Amongst those with type 1 diabetes, 35% were managing their diabetes with an insulin pump. Amongst those with type 2 diabetes, 42% were using insulin. Most respondents spoke English as their main language (97%), were married or in a de facto relationship (68%), had vocational or university qualifications (66%), lived in metropolitan areas (61%), were in paid employment (54%), and had an annual household income of more than AU$40,000 per annum (54%).

Tight confidence intervals of 2.02 were evident (calculated using a worst-case scenario proportion of 50%, a 95% confidence level, and sample size of 2,342), providing evidence of sample adequacy.

Table 1: Sample characteristics for the 2015 Diabetes MILES – Australia survey, by diabetes type*

	Type 1 diabetes n=1,078 (46)	**Type 2 diabetes** n=1,264 (54)	**Total sample** N=2,342 (100)
Gender - female	639 (59)	539 (43)	1178 (50)

Age - years	44±15 (18-75)	61±9 (22-75)	53±15 (18-75)
Diabetes duration - years	19±14 (0-68)	11±7 (0-44)	15±12 (0-68)
Primary diabetes management			
Insulin pump therapy	380 (35)	2 (0.2)	382 (16)
Insulin injections	698 (65)	529 (42)	1227 (52)
Non-insulin injectables	-	47 (4)	47 (2)
Blood glucose lowering tablets	-	510 (40)	510 (22)
Diet and/or exercise alone	-	176 (14)	176 (8)
Aboriginal or Torres Strait Islander	14 (1)	22 (2)	36 (2)
Main language spoken at home - English	1054 (98)	1214 (96)	2268 (97)
Country of birth - Australia	831 (77)	889 (70)	1720 (73)
Relationship status			
Single	241 (22)	111 (9)	352 (15)
In a steady relationship	52 (5)	21 (2)	73 (3)
Married or De-Facto	706 (66)	891 (71)	1597 (68)
Separated	18 (2)	36 (3)	54 (2)
Divorced	48 (4)	130 (10)	178 (8)
Widowed	8 (1)	71 (6)	79 (3)
Education			
No qualifications	30 (3)	125 (10)	155 (7)
School/Intermediate certificate	105 (10)	205 (16)	310 (13)
High School/Leaving certificate	181 (17)	140 (11)	321 (14)
Trade training or diploma(s)	252 (23)	382 (30)	634 (27)
University undergraduate degree	269 (25)	223 (18)	492 (21)
Higher university degree	236 (22)	185 (15)	421 (18)
(Un)Employment details			
Paid employment	770 (72)	477 (38)	1247 (54)
Retired	146 (14)	579 (46)	725 (31)
Full-time student	26 (2)	8 (1)	34 (2)
Unpaid household duties	40 (4)	49 (4)	69 (3)
Unemployed	86 (8)	146 (12)	232 (10)
Other	8 (1)	4 (0.3)	12 (1)
Annual household income ($AUD)			
≤20,000	130 (12)	225 (18)	355 (15)
20,001 – 40,000	123 (12)	281 (23)	404 (17)
40,001 – 60,000	135 (13)	199 (16)	334 (14)
60,001 – 100,000	240 (23)	175 (14)	415 (18)
100,001 – 150,000	158 (15)	113 (9)	271 (12)
>150,000	123 (12)	75 (6)	198 (9)
Don't know / prefer not to say	155 (15)	177 (14)	332 (14)
State			
Australian Capital Territory	54 (5)	132 (10)	186 (8)
New South Wales	345 (32)	258 (20)	603 (26)
Northern Territory	9 (0.8)	41 (3)	50 (2)
Queensland	140 (13)	143 (11)	283 (12)
South Australia	86 (8)	120 (10)	206 (9)
Tasmania	50 (5)	120 (10)	170 (7)
Victoria	281 (26)	297(24)	578 (25)
Western Australia	113 (10)	151 (12)	264 (11)
Geographical location			
Metropolitan	483 (63)	750 (60)	1433 (61)

Regional	272 (25)	303 (24)	575 (25)
Rural	122 (11)	206 (16)	328 (14)

Data are n (%) or mean±SD (range)

* Total N reported is not always consistent with total sample size due to missing data for some variables. Percentages do not always sum to 100 due to rounding.

Table 2 compares the sample characteristics of the longitudinal and 2015 new cohorts. With few exceptions, the longitudinal and new cohorts were equivalent on key socio-demographic and clinical characteristics, indicating that the cohorts may be pooled for future analyses. On average, participants with type 1 diabetes in the longitudinal cohort were older and had a longer diabetes duration than the new cohort, but while the difference was significant, it was not notable (<5 year mean difference in both instances). Respondents with type 1 diabetes in the longitudinal cohort were more likely to be using an insulin pump than those in the new cohort. Regardless of diabetes type, compared with the new cohort, the longitudinal cohort was more likely to have a university education, less likely to have no qualifications, and more likely to reside in the state of Victoria.

Table 2: Sample characteristics by cohort*

	Longitudinal Cohort	**2015 new Cohort**	**Sig**
Total eligible sample	**504 (22)#**	**1838 (79)**	
Gender – female	261 (52)	917 (50)	ns
Diabetes type			ns
Type 1 diabetes	236 (47)	842 (46)	
Type 2 diabetes	268 (53)	996 (54)	
Age – years			
Type 1 diabetes	47±14	43±16	<.001
Type 2 diabetes	62±8	61±10	ns
Diabetes duration – years			
Type 1 diabetes	22±14	18±14	<.001
Type 2 diabetes	12±7	11±8	ns
Primary treatment for type 1 diabetes			<.001
Insulin pump therapy	106 (45)	274 (33)	
Insulin injections	130 (55)	568 (67)	
Primary treatment for type 2 diabetes			ns
Insulin pump therapy	0 (0)	2 (0.2)	
Insulin injections	95 (35)	434 (44)	
Non-insulin injectables	11 (4)	36 (4)	
Blood glucose lowering tablets	119 (44)	391 (39)	
Diet and/or exercise alone	43 (16)	133 (13)	
Aboriginal or Torres Strait Islander origin	5 (1)	31 (2)	ns
Main language spoken at home - English	494 (98)	1774 (97)	ns
Country of birth – Australia	387 (77)	1333 (73)	ns
Relationship status			ns
Single	64 (13)	288 (16)	
In a steady relationship	12 (2)	61 (3)	
Married or De-Facto	356 (71)	1241 (68)	
Separated	12 (2)	42 (2)	
Divorced	44 (9)	134 (7)	
Widowed	15 (3)	64 (3)	

Education			
No qualifications	15 (3)	140 (8)	<.001
School/Intermediate certificate	68 (14)	242 (13)	
High School/Leaving certificate	58 (12)	263 (14)	
Trade training or diploma(s)	132 (26)	502 (28)	
University undergraduate degree	123 (25)	369 (20)	
Higher university degree	106 (21)	315 (17)	
(Un)Employment details			
Paid employment	280 (56)	967 (53)	ns
Retired	155 (31)	570 (31)	
Full-time student	6 (1)	28 (2)	
Unpaid household duties	26 (5)	63 (3)	
Unemployed	35 (7)	197 (11)	
Other	2 (0.4)	10 (1)	
Annual household income ($)			
≤20,000	67 (13)	288 (16)	ns
20,001 – 40,000	79 (16)	325 (18)	
40,001 – 60,000	80 (16)	254 (14)	
60,001 – 100,000	94 (19)	321 (18)	
100,001 – 150,000	61 (12)	210 (12)	
>150,000	57 (11)	141 (8)	
Don't know / prefer not to say	65 (13)	267 (15)	
State			
Australian Capital Territory	17 (3)	169 (9)	<.001
New South Wales	105 (21)	498 (27)	
Northern Territory	1 (0.2)	49 (3)	
Queensland	81 (16)	202 (11)	
South Australia	25 (5)	181 (10)	
Tasmania	12 (2)	158 (9)	
Victoria	215 (43)	363 (20)	
Western Australia	47 (9)	217 (12)	
Geographical location			
Metropolitan	312 (63)	1121 (61)	ns
Regional	127 (25)	448 (24)	
Rural	63 (13)	265 (14)	

Data are n (%) or mean±SD (range)

*Table refers only to eligible participants. Total N reported is not always consistent with total sample size due to missing data on some items. Percentages do not always sum to 100 due to rounding.

#Of the 504 longitudinal cohort participants, 459 could be matched with 2011 data.

Depth and breadth of available data

Consistent with the aims of the Diabetes MILES Study initiative, the data available primarily relate to the psychological (e.g. emotional well-being), behavioural (e.g. self-management) and social (e.g. diabetes stigma) aspects of living with diabetes. These data make possible the assessment of prevalence, relationships between key variables, and (in the longitudinal cohort), change over time and associations between exposure to a new condition and key outcomes. The survey included validated scales, study-specific individual items and newly developed measures (for validation). For 'core' constructs (e.g. general and diabetes-specific emotional well-being), the measures used in 2011 were included in the 2015 survey. This was important in order to generate a longitudinal data set for assessing within-group change over time, but also to enable comparison on key issues of the full 2011 and 2015 study samples as representative 'snapshots' of the Australian population of adults with diabetes.

While the 2011 and 2015 surveys had similar content, they were not identical. Some measures (e.g. Resources and Support for diabetes Self Management questionnaire) were not repeated in 2015 because ongoing data collection on the topic was not considered a key priority. Some measures were replaced with another measure of the same construct (e.g. the Diabetes Self-Care Inventory – Revised was replaced with the Summary of Diabetes Self-Care Activities[55]). Some measures were replaced with a shorter version to reduce respondent burden (e.g. the Quality of Life Questionnaire was replaced with the DAWN Impact of Diabetes Profile[5]). Finally, some measures were replaced with measures tailored to diabetes type and/or treatment (e.g. the Diabetes Empowerment Scale Short-Form[56] was replaced with the Confidence in Diabetes Self-care scale, with insulin-using[57] and non-insulin using[58] versions.

In the original (2011) Diabetes MILES study, two alternate survey versions (A and B) were used. To ensure that all longitudinal cohort participants had complete data sets for key variables (e.g. diabetes-specific distress), their 2015 survey content was tailored automatically (based on the unique code they entered) to match the survey version they completed in 2011. However, this automatic tailoring was not possible for those completing the hard copy surveys (n=27), and thus they were treated as new cohort participants.

Survey content was grouped by theme into eight sections: 1) Demographics, 2) My General Well-being, 3) My Feelings about Diabetes, 4) My General Health, 5) Support from Health Professionals, Family and Friends, 6) My Diabetes, 7) My Blood Glucose Levels, 8) My Thoughts and Beliefs. It was also tailored to diabetes type and treatment (based on information provided in the Demographics section of the survey) and as such, not all measures were presented to every participant. Table 3 summarises the topics/constructs, variables and measures used in the 2015 MILES-2 survey (for both the new and longitudinal cohorts separately), and also indicates which of the same content was included in the 2011 survey.

Table 3. Survey content for the 2015 Diabetes MILES – Australia survey

Concept/topic	Measure or variable	2015 new cohort	Longitudinal cohort	2011 survey
Demographics				
Eligibility screen	Diabetes type, age, live in Australia	✓	✓	✓
Demographic & socioeconomic details	Gender, state, postcode, country of birth, language, marital status, living situation, income, employment, education			
Diabetes details	Diabetes duration, diabetes treatment			
Other	Diabetes organisation membership, how they heard about survey			
My General Well-being				
General emotional well-being	World Health Organisation Well-being Index (WHO-5)[59]	✓	✓	✓
	General life satisfaction (single item)[60]			
Depressive symptoms	Patient Health Questionnaire (PHQ-8)[61]			
Anxiety symptoms	Generalised Anxiety Disorder scale (GAD-7)[62]			
My Feelings About Diabetes				
Diabetes-specific distress	Problem Areas In Diabetes Scale (PAID)[63]	✓	✓*	✓*
	Diabetes Distress Scale (DDS)[64]		✓^	✓^
	Type 1 Diabetes Distress Scale (T1-DDS)[65]		✓^#	

Diabetes-related and generic stigma	Type 1 and Type 2 Diabetes Stigma Assessment Scales (DSAS-1[66]; DSAS-2[67])	✓	✓*	
	Stigma Scale for Chronic Illnesses – 8 item version (SSCI-8)[68]	✓	✓*	
	6 study-specific items about portrayal of diabetes in the media	✓	✓	
Quality of life	DAWN Impact of Diabetes Profile (DIDP)[5]	✓	✓	
Illness centrality	Centrality Scale[69]	✓	✓	
My General Health				
Health background	Physical and mental health comorbidities and complications, height and weight, smoking status, health insurance and pension	✓	✓	✓
Weight stigma	Weight Self-Stigma Questionnaire (WSSQ)[70]	✓	✓	
Memory	Prospective and Retrospective Memory Questionnaire (PRMQ)[71]	✓	✓	
Support from Health Professionals, Family and Friends				
Healthcare	Access to providers in last 12 months, main provider, group structured education	✓	✓	✓
Social support	Diabetes Support Scale (DSS)[72]	✓	✓	
	Social Support subscale of Diabetes Care Profile (DCP)[73]	✓	✓	
Peer support	Study-specific items	✓	✓	
My Diabetes				
Self-care	Diet and physical activity subscales of the Summary of Diabetes Self-Care Activities (SDSCA)[55]	✓	✓	
	Study-specific items: dietary behaviours	✓	✓	
	Study-specific items: physical activity behaviours	✓	✓	
	Study-specific items: blood glucose monitoring	✓	✓	
	Modified Importance and Burden items (for diet, physical activity, blood glucose monitoring) from the Summary of Diabetes Self-Care Inventory – Revised (unpublished)	✓	✓	
Diabetes treatment	Study-specific items assessing frequency/time of day for injections/bolusing, frequency of forgetting and skipping injections/bolus/medication dose, reasons for forgetting/skipping	✓	✓	
HbA1c	Study-specific items	✓	✓	✓
App use for self-management support	Study-specific items	✓	✓	
Diabetes-specific self-efficacy	Confidence In Diabetes Self-Care (CIDS) (insulin-using[57] and non-insulin-using versions[58])	✓	✓	
Psychological insulin resistance	Insulin Treatment Appraisal Scale (ITAS)[74]	✓~	✓~	✓~
	'Willingness to begin insulin' single item[75]	✓~	✓~	
My Blood Glucose Levels				
Hyperglycaemia	Two items adapted from the Hyperglycaemia Avoidance Scale (HAS)[76]	✓#	✓#	
Hypoglycaemia	Study-specific items (some based on the Hypoglycaemia Awareness	✓	✓	✓

	Questionnaire[77]) to assess frequency, hospitalisation, insulin adjustment in response to hypoglycaemia, impaired awareness of hypoglycaemia			
	Edinburgh Hypoglycaemia Survey (EHS)[78]	✓	✓	
	Gold Score[79]	✓	✓	✓
My Thoughts and Beliefs				
Self-esteem	Rosenberg Self-Esteem Scale (RSE)[80]	✓	✓	
Self-compassion	Self-Compassion Scale Short Form (SCS-SF)[81]	✓	✓	
Other	Free-text box inviting participants to make any other comments	✓	✓	✓

*Participants who completed survey B version in 2011 only. ^Participants who completed survey A version in 2011 only. #Participants with type 1 diabetes only. ~Participants with type 2 diabetes only.

FINDINGS TO DATE

Sample stratification

The success of the stratified sampling approach was assessed by comparing the sub-sample of new cohort respondents who indicated that they received an invitation direct from the NDSS against the planned stratification (described in Methods). Respondents with type 1 diabetes were slightly over-represented in the new cohort (45%) relative to the planned stratification (40% type 1 diabetes, 60% type 2 diabetes). Relative to the planned stratification for state (designed to reflect the proportion of NDSS registrants per state), there was evidence of over-sampling of participants in the Australian Capital Territory (3% invited versus 11% response), New South Wales (21% versus 26%), the Northern Territory (1% versus 3%) and Tasmania (3% versus 10%). Under-sampling of participants was evident in Queensland (19% invited versus 12% response), South Australia (16% versus 11%), Victoria (20% versus 15%), and Western Australia (17% versus 12%). Respondents with insulin-treated type 2 diabetes were under-represented in the new cohort relative to the stratified sampling (42% invited versus 50% response).

Longitudinal cohort data matching

Of the 504 eligible participants who completed the longitudinal cohort survey, 459 (91%) were matched with their original 2011 data. The representativeness of the longitudinal dataset compared to the original 2011 sample can be assessed by comparing the sample characteristics of those who took part in both 2011 and 2015 with those who took part in 2011 only. As shown in Table 4, participants who completed both the 2011 and 2015 surveys were slightly more likely than those completing the 2011 survey only to have type 1 diabetes, report a higher education and annual income, and live in metropolitan regions of Australia. For those with type 1 diabetes, those who participated in both the 2011 and 2015 surveys had a longer mean diabetes duration relative to those who took part in 2011 only. Among those with type 2 diabetes, the reverse was true: participants of both the 2011 and 2015 surveys had a shorter mean diabetes duration compared to those who took part in 2011 only.

Table 4: Baseline characteristics of longitudinal survey completers (2015 and 2011) versus non-completers (2011 only) *

	2011 only (cross-sectional) cohort	2011 & 2015 (longitudinal) cohort	Sig
TOTAL	**2879 (86)**	**459 (14)**	
Gender - female	1538 (54)	240 (53)	ns
Diabetes type			
Type 1 diabetes	1157 (40)	219 (48)	.002
Type 2 diabetes	1722 (60)	240 (52)	
Age - years			
Type 1 diabetes	42±14	43±13	ns
Type 2 diabetes	59±9	57±8	.016
Diabetes duration - years			
Type 1 diabetes	15±13	18±14	.001
Type 2 diabetes	9±7	8±6	.030
Primary treatment for type 1 diabetes			
Insulin pump therapy	246 (21)	79 (36)	<.001
Insulin injections	902 (79)	140 (64)	
Primary treatment for type 2 diabetes			
Insulin pump therapy	8 (0.0)	0 (0)	
Insulin injections	642 (39)	72 (30)	
Non-insulin injectables	15 (1)	7 (3)	.002
Blood glucose lowering tablets	767 (45)	109 (45)	
Diet and/or exercise alone	266 (16)	52 (22)	
Aboriginal or Torres Strait Islander origin	47 (2)	2 (0.0)	.037
Main language spoken at home - English	2759 (97)	446 (98)	ns
Country of birth - Australia	2119 (74)	354 (77)	ns
Relationship Status			
Single	391 (14)	59 (139)	
In a steady relationship	105 (4)	20 (4)	
Married or De-Facto	1945 (69)	325 (71)	ns
Separated	77 (3)	6 (1)	
Divorced	216 (8)	39 (9)	
Widowed	89 (3)	7 (2)	
Education			
No qualifications	254 (9)	12 (3)	
School/Intermediate certificate	308 (11)	34 (8)	
High School/Leaving certificate	552 (20)	79 (18)	<.001
Trade training / certificate/ diploma	848 (31)	135 (30)	
University undergraduate degree	474 (18)	108 (24)	
Higher university degree	271 (10)	81 (18)	
In paid employment	1654 (57)	310 (68)	<.001
Annual household income ($)			
≤20,000	539 (20)	57 (13)	
20,001 – 40,000	500 (19)	59 (13)	
40,001 – 60,000	502 (19)	79 (18)	<.001
60,001 – 100,000	579 (21)	120 (27)	
100,001 – 150,000	346 (13)	81 (18)	
>150,000	228 (8.)	52 (12)	

Geographical location			<.001
Metropolitan	1425 (51)	275 (61)	
Regional	808 (29)	116 (26)	
Rural	587 (21)	63 (14)	

Data are n (%) or mean±SD (range)
*Data from 2011 Diabetes MILES – Australia.

Qualitative findings

The qualitative data provided by participants in the free-text boxes indicated that in general, the survey was highly acceptable to participants. While some participants felt the survey was *"too long"*, others were appreciative for the *"comprehensive"* and *"thoughtful"* nature of this research. For many, it promoted further learning about diabetes, and a chance to reflect on their attitudes to living with diabetes:

> "*Doing this survey makes me realise that I could access support networks/ forums/ health care practitioners more than I actually do"* (woman, 31 years, type 1 diabetes)

Some participants perceived that *"psychological support doesn't exist"* (woman, 25 years, type 1 diabetes) for their diabetes-related concerns, and therefore were pleased that this work was being conducted:

> *"I would like to say thank you for this survey, as it's good to know that there are people concerned with diabetes and the issues we may have"* (man, 67 years, type 2 diabetes)

STRENGTHS AND LIMITATIONS

Strengths

Key strengths of MILES-2 are the breadth and depth of quantitative data and the large, population-based sample size that will afford the necessary statistical power to investigate sub-groups and conduct multivariate analyses. Our confidence interval calculations confirm that this sample size is adequate to facilitate relatively accurate estimations of population-level statistics. While clinical and biomedical research abounds in the field of diabetes, there is a pressing need for an increased research focus on the psychosocial aspects of the condition[27]. MILES-2 contributes to this gap in our knowledge by providing a rich dataset that combines cross-sectional and longitudinal assessment of key topics such as emotional well-being, self-management, and healthcare access, as well as introducing novel topics of investigation such as social stigma, cognition and memory, and self-compassion. The qualitative feedback from participants indicated that the topics included in the survey were relevant to them, and the survey was generally very well received.

The survey was conducted primarily online, with only 27 of the 2,342 respondents (1%) asking to complete a hard copy version. The online survey methods were successful in generating a sample with gender balance, a wide age range, diverse socio-economic backgrounds, and a representative mix of people living in metropolitan, regional, and rural areas in all states and

territories of Australia. The online survey was a successful and economical approach to surveying a wide range of Australian adults with diabetes, all within a relatively short time period (seven weeks).

The significance of the emerging longitudinal dataset is particularly noteworthy. For the first time, it will be possible to explore predictors and consequences of psychological distress and sub-optimal behavioural diabetes management in a non-clinical, population-based sample. It represents the first attempt to track the natural trajectory of emotional problems in people with diabetes (e.g. diabetes distress) and to investigate any social, economic, and/or demographic factors that may contribute to variation in psychological experiences. This in turn will enable better tailoring of interventions to meet those with greatest need. It is our intention to conduct further surveys in the future to continue to follow all respondents who have indicated willingness to continue their participation. This will enable us to build on the existing longitudinal dataset using a third wave of data collection, and to increase the sample size and breadth of survey topics available in the longitudinal cohort.

Limitations

Response rates

The response rates for both the longitudinal and the new cohorts in the MILES-2 survey were low; the longitudinal cohort had a markedly better response rate (26%) than the 2015 new cohort (8%). It is possible that respondents who agreed to take part in future surveys in 2011 had a higher level of commitment to and interest in the Diabetes MILES Study due to their previous participation.

In the longitudinal cohort, substantial attrition was evident between the 2011 and 2015 surveys, and the response rate is notably lower than other health-related longitudinal Australian surveys[82, 83]. However, these other initiatives were very well resourced, enabling many repeat attempts at contact using various methods. For MILES-2, only two contacts were possible (invitation plus one reminder). Further, MILES-2 focused specifically on adults with type 1 or type 2 diabetes aged 18-75, whereas in contrast, the other initiatives sampled the general population and did not focus on a particular condition. It has been noted that the population being sampled is the most important determining factor for survey response rates[84], and thus comparison of the MILES-2 response rate with other Australian general population surveys is not necessarily appropriate. People with diabetes are more likely than the general population to have serious physical and mental health comorbidities[12, 13, 85, 86], impaired general well-being[33], and those with type 2 diabetes are more likely to be socioeconomically disadvantaged[87], making non-response and problematic attrition more likely[88, 89].

Another possible explanation for the relatively high rate of attrition between the 2011 and 2015 surveys is the different methods of recruitment and data collection. In 2011, participants received a hard copy survey; online survey completion was possible but 70% of 2011 survey respondents completed the hard copy version. In contrast, the 2015 survey was online by default, and respondents needed to request a hard copy. This may have created too many barriers to participation for some, leading to non-response.

The response rate of the 2015 new cohort is low at 8%, and considerably lower than the 18% observed in the 2011 survey[29]. However, a number of factors may explain this. First, as noted

above, the default online data collection may have been a barrier to participation. Second, the survey took place at a time when NDSS registrants were being contacted frequently for research purposes, which was not the case in 2011. On the advice of the NDSS, the survey launch date was pushed back from November 2014 to March 2015 in an attempt to avoid survey fatigue. However, the low response rate suggests that this delay was insufficient and that NDSS registrants may have been burdened by too many research participation requests. Finally, online surveys are now prolific, and decreasing response rates have been noted elsewhere[84]. Thus, the low response rate observed in the 2015 new cohort of the MILES-2 survey may be reflective of a broader trend, compounded by the challenges faced by this population as already described.

In spite of the low response rates, as noted above, the sample sizes obtained are more than adequate to facilitate inferential data analyses, and to draw conclusions about the unmet needs of Australian adults with type 1 and type 2 diabetes.

Stratification of the new cohort sample

The sampling for the new cohort was stratified by diabetes type, insulin use (type 2 diabetes only), and Australian state of residence. Respondents with type 1 diabetes were slightly over-represented in our sample (45%) relative to the stratification (40%). This may reflect a generally higher level of engagement in diabetes-related activities and advocacy in this group relative to those with type 2 diabetes.

Amongst respondents with type 2 diabetes, 42% were using insulin which is almost double the proportion observed on the NDSS database (24%), but less than anticipated given the purposeful sampling stratification (50%). Based on our previous research, Australian adults with type 2 diabetes who use insulin (compared with those not using insulin) have a longer diabetes duration[90], are more likely to have at least one diabetes-related complication[31, 32], and are more likely to have depressive and anxiety symptoms[43]. These factors may make them less likely to engage in research initiatives[88, 89].

Sample representativeness

The NDSS is considered to be one of the best national sources of data about Australians with diabetes[91], and thus the representativeness of our study sample can best be determined by comparing our sample characteristics with the NDSS registrant database characteristics. Notwithstanding the purposeful stratification and oversampling of adults with type 1 diabetes and those with insulin-treated type 2 diabetes, the gender balance was broadly representative of people registered on the NDSS database[90]. Overall, men and women were represented equally in the sample (50% men; 50% women) and the proportions in our sample approximate the NDSS register (52% men versus 48%).

Amongst those with type 1 diabetes, 35% were using an insulin pump to manage their diabetes. As only 10% of adults with type 1 diabetes registered with the NDSS use an insulin pump [92], it appears that this group is over-represented in our sample. While insulin pump users were intentionally over-sampled in the 2011 survey this was not the case for the 2015 new cohort, and yet they were over-represented in the sample anyway. The over-representation of pump users is consistent with research participation patterns observed in similar studies[44, 45].

Pump users may be more engaged in research because they perceive themselves to benefit from advances in knowledge, or it may be reflective of the fact that pump users tend to be more highly educated and from higher socio-economic backgrounds relative to non-pump users[92].

Compared with the Australian general population, our sample was more likely to speak English as their main language[93], to be married or in a de facto relationship[94], to be in paid employment[95], and have post-high school qualifications[96]. This indicates that those who took part are a relatively privileged sample with significant social resources who are likely to have better health literacy and access to health services than Australians with diabetes generally. Self-selection bias is commonly observed in web-based studies[97, 98], and may result in the under-estimation of social and emotional problems, and problems of healthcare access. In the context of the MILES-2 study, this bias must be acknowledged as a considerable limitation that may threaten the generalisability of the data to the broader Australian population of adults with diabetes. Weighting of cases may be adopted for future analyses, depending on the sub-sample and outcome variables being used. As a key focus of future inferential analyses of the MILES-2 data will be the relationships between variables, the self-selection bias is likely to have minimal impact on this if cases are weighted accordingly. For future MILES studies, consideration will be given to strategies that will address the under-sampling of participants from less advantaged backgrounds such as community outreach through health professionals and diabetes clinics, collaborating with researchers with expertise in working with Aboriginal and Torres Strait Islander communities, and stronger promotion of the availability of hard copy versions of the survey.

FUTURE DIRECTIONS AND COLLABORATIONS

Subject to funding availability, we plan ongoing follow-up (approximately every four years) of the longitudinal cohort, and we expect to be able to grow both the cohort and the depth and breadth of data available by also conducting follow-up MILES surveys with the 2015 new cohort. To maintain participant engagement and therefore aid retention, we are currently writing a report that summarises top-level findings of the study for a lay audience. All MILES-2 participants were given the opportunity to opt to receive a free electronic copy of the report when it becomes available.

One key direction for future data analysis and publication is examination of within-participant changes between 2011 and 2015 on variables such as depressive and anxiety symptoms, diabetes distress, and insulin appraisals. Additional priority avenues of enquiry will include identifying the psychological and behavioural correlates of diabetes distress, hypoglycaemia avoidance, and depressive symptoms to inform intervention development, exploring associations with diabetes stigma and psychological and behavioural outcomes, characterising the use of technologies (e.g., smartphone apps) to aid self-management, and psychometric analysis of scales that have not previously been used in an Australian context (e.g. DIDP). Findings from MILES-2 will be disseminated through academic publications, conference presentations, health professional training and community symposia over several years.

We encourage collaborations from researchers with relevant expertise in the field. Researchers may gain access to the second Diabetes MILES – Australia survey dataset upon submission of a proposal detailing the topics of interest, key research questions, and hypotheses. Proposals will

be evaluated by the Diabetes MILES Study research team on the basis of feasibility, relevance, novelty, and expertise of the researchers. Enquires should be directed to Dr Jessica Browne (first author).

CONCLUSIONS

The second Diabetes MILES – Australia study builds on the previous Diabetes MILES Study initiatives to deliver Australia's first large-scale longitudinal assessment of the psychosocial aspects of type 1 and type 2 diabetes, and to introduce novel topics of investigation at a population level. The depth and breadth of the data available in this large sample will raise further awareness of the psychosocial impact of living with type 1 and type 2 diabetes, will highlight unmet needs and priority areas for future investigation, and crucially, will inform policy, program and intervention development and evaluation.

FURTHER DETAILS

Ethics approval and consent to participate

This study was approved by the Deakin University Human research Ethics Committee (2011-046). All participants provided informed consent.

Data sharing statement

The second Diabetes MILES – Australia survey dataset is available for analysis by researchers with interest and expertise in this field. For further information, please contact: jbrowne@acbrd.org.au

Competing interests

All authors have completed the ICMJE uniform disclosure at www.icmje.org/coi_disclosure.pdf and declare: financial support for the submitted work from Sanofi ANZ in the form of an unrestricted educational grant; JB has done consultancy work for Sanofi ANZ, has served on a Sanofi ANZ advisory board, and has had travel expenses covered by Sanofi ANZ, with all monies given to her institution. FP has served on an advisory board for Sanofi-Aventis, with monies paid to him personally. JS has done consultancy work for Sanofi ANZ and has had travel expenses covered by Sanofi ANZ, with all monies paid to her institution. EHT, ADV, and CH have no relevant conflicts of interest to declare.

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Author's contributions

JS conceived The Diabetes MILES Study, and together with FP developed The Diabetes MILES Study International Collaborative. All authors contributed to the development of the study design and survey content. JB project managed MILES-2, and wrote the first draft of this manuscript with substantial input from EHT. All authors provided substantial intellectual contributions to the manuscript by providing feedback on drafts. All authors approved the final manuscript.

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Appendix 1. CHERRIES checklist for MILES-2 online survey

Item category	Checklist item	Description
Design		Online survey comprising two elements: 1) longitudinal follow-up of the original 2011 MILES study participants, and 2) cross-sectional assessment of a new cohort of participants. All participants were Australian adults with type 1 or type 2 diabetes aged 18-75. The longitudinal cohort were contacted directly be researchers (with their prior consent) to be invited to take part. Participants for the new cohort element were randomly sampled (with stratification by diabetes type and treatment, and state of residence) from the National Diabetes Services Scheme (NDSS). The study was also advertised nationally to supplement the NDSS sampling for the new cohort. The longitudinal and new cohort survey versions were near identical. Hard copy surveys were made available, via post, to those who requested it. Participants completing hardcopy surveys were included in the new cohort sample.
Ethics	Ethics approval	The study was approved by the Deakin University Human research Ethics Committee (2011-046).
	Informed consent	The first survey screen was a detailed plain language description of the study that outlined the study aims, procedure, how long the survey would take, how data would be stored, and what would be done with their information. Participants indicated informed consent by ticking a box. Only after providing informed consent did the participant have access to the survey proper.
	Data protection	Secure survey software and secure, password-protected Deakin University servers were used to ensure data were protected. The dataset has been de-identified, with all possible identifying information stored separately to the data file.
Development and pre-testing		The survey content was informed by the original 2011 MILES survey. Where modifications were made, these decisions were based on thorough review of the literature and discussion with the research team until consensus was reached. The technical functionality and flow of the survey was extensively tested by the research team prior to finalisation.
Recruitment process	Open vs closed survey	The longitudinal element of the study was closed. The new cohort element of the study was open.
	Contact mode	Participants from the original 2011 MILES survey who had consented to be contacted were mailed/emailed a study invitation by the researchers with a unique log-in code to the online survey that was used to match their data with the previous survey data. Participants in the new cohort who

		were sampled through the NDSS received a letter of invitation in the mail directly from the NDSS. Participants in the new cohort who saw the study advertised elsewhere were provided with the study URL so they could enter the survey directly.
	Advertising the survey	The survey was advertised in various diabetes-related print, electronic and social media. Participants who responded to the study from these advertisements entered the new cohort.
Survey administration	Web/email	This was a web-based survey, hosted by Qualtrics™. Participants accessed the survey by first visiting the Diabetes MILES Study website, and then clicking a button to open up the Qualtrics™-hosted survey.
	Context	To access the survey, participants were first directed to a website dedicated to providing information about the Diabetes MILES Study (www.diabetesMILES.org). From this website, they would click a button to open up the Qualtrics™-hosted survey.
	Mandatory/voluntary	Participation was voluntary, and this was outlined to participants during the informed consent process.
	Incentives	Participants were entered into a prize draw to win one of three iPad minis™.
	Time/date	Data were collected between March – May 2015.
	Item randomisation	Not used.
	Adaptive questioning	Branching was used to tailored the survey to diabetes type and treatment, and also to follow up with further questioning conditional to prior responses. For example, participants were first asked if they had ever experienced a hypoglycaemic episode. If they answered yes, a series of additional questions were presented about their experiences of a hypoglycaemic episode(s).
	Number of items	The number of items per page varied between 1 – 48 (with multiple items presented in one table with response required on the same Likert scale).
	Number of screens	Varied widely according to eligibility, survey version and branching.
	Completeness check	Items requiring input for the purposes of tailoring the survey to diabetes type and treatment were mandatory. All other items were optional, but if a participant skipped a question, it was highlighted to them before they moved to the next screen. They could then choose to leave the response blank, or return to the skipped question to provide a response.
	Review step	Participants could not review or change their responses once they moved on to the next screen.

Response rates	Unique site visitor	Unique visitors were determined by IP address, and double-checking identified duplicates were true duplicates on the basis of their demographic information.
	View rate	Necessary detail for calculation was not recorded.
	Participation rate	The response rate to invitations for the new cohort was 8%. The response rate for the longitudinal cohort was 26%. However, the necessary detail to calculate participation rate (those who started the survey versus those who opted out prior to opening the Qualtrics™ site and/or providing informed consent was not recorded.
	Completion rate	0.88 (88%)
Preventing multiple entries from same individual	Cookies used	No.
	IP check	Yes.
	Log file analysis	Not used.
	Registration	Only for the longitudinal cohort participants. They entered a unique code that was used to match their survey responses with their prior data.
Analysis	Handling of incomplete questionnaires	Participant data was used regardless of whether they completed the full survey. For validated scales, small amounts of missing data were tolerated (based on a priori decisions which varied by scale), with expectation-maximisation imputation being used to facilitate calculation of total scores. Participants who had more missing data on a scale than was tolerated were not given a total score for that scale.
	Questionnaires with atypical timestamp	No atypical timestamps were detected.
	Statistical correction	None required.