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Research: Educational and Psychological Issues

The INTERPRET–DD study of diabetes and depression: a protocol

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Abstract

Aim People with diabetes are at an increased risk of developing depression and other psychological disorders. However, little is known about the prevalence, correlates or care pathways in countries other than the UK and the USA. A new study, the International Prevalence and Treatment of Diabetes and Depression Study (INTERPRET–DD) aims to address this dearth of knowledge and identify optimal pathways to care across the globe.

Method INTERPRET–DD is a 2-year longitudinal study, taking place in 16 countries' diabetes outpatients' facilities, investigating the recognition and management of depressive disorders in people with Type 2 diabetes. Clinical interviews are used to diagnose depression, with clinical and other data obtained from medical records and through patient interviews. Pathways to care and the impact of treatment for previously unrecognized (undocumented) depression on clinical outcomes and emotional well-being are being investigated.

Results Initial evidence indicates that a range of pathways to care exist, with few of them based on available recommendations for treatment. Pilot data indicates that the instruments we are using to measure both the symptoms and clinical diagnosis of depression are acceptable in our study population and easy to use.

Conclusions Our study will increase the understanding of the impact of comorbid diabetes and depression and identify the most appropriate (country-specific) pathways via which patients receive their care. It addresses an important public health problem and leads to recommendations for best practice relevant to the different participating centres with regard to the identification and treatment of people with comorbid diabetes and depression.

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What's new?

- Comorbid diabetes and depression is costly – both to the individual and to society and is an important public health problem.
- Little is currently known about the pathways to care for mental health problems in people with Type 2 diabetes in countries other than the UK, Australia and the USA.
- This study will investigate the prevalence, correlates and pathways to care for people with diabetes and depression in 16 countries across the globe where current evidence does not exist.
- These data will inform healthcare practice relevant to the different participating centres where current evidence is lacking with regard to the identification and treatment of people with comorbid diabetes and depression.

Introduction

In 2011, the 65th World Health Assembly adopted a resolution that identified an urgent need for a 'comprehensive, coordinated response' at the country level in order to address the global burden of mental disorders (www.who.int/mental_health/WHA65.4_resolution.pdf). Depressive disorders have been singled out as an important aspect of this, with the WHO World Bank Report on Disability [1] identifying depression as the third most important cause of disability in the world. Depressive disorders are experienced by individuals regardless of culture, gender or socioeconomic status, however, those with a physical disease are more likely to have depression. The World Health Survey estimated the prevalence of comorbid depression (based on ICD–10 criteria) from examinations of 245 404 individuals from 60 countries around the world and found prevalence rates in people with one or more chronic physical diseases to be between 9.3–23% [2]. Self-reported health status was significantly poorer in those with comorbid diabetes and depression compared with individuals with any other chronic disease [2].

The risk of developing mental health problems, including depression, anxiety and other forms of emotional and psychological distress, is known to be increased in people with Type 2 diabetes [3]. To date, however, research in this field has mainly been cross sectional and conducted in the USA [4], for example, the Pathways study [5], with few studies being conducted in other countries, albeit with notable exceptions such as the TrueBlue study in Australia [6]. Longitudinal studies are scarce and so causal pathways and care processes have yet to be determined. Available studies have suggested that the prognosis of both diabetes and depression – in terms of severity of disease, complications, treatment resistance and mortality – is worse for either disease when they are comorbid than when they occur separately [7–9]. In these circumstances, they are often more likely to be managed in secondary care although existing research has focused on primary care provision. Despite recent increased interest in the associations between diabetes and depression, knowledge and understanding of the relationship between the two conditions remains extremely poor internationally, where health systems differ and treatment and referral patterns vary. Depressive disorders in people with Type 2 diabetes remain underdiagnosed and undertreated and the care pathways that do exist are largely undocumented.

Up to one third of people with diabetes suffer from subthreshold or major depressive disorders (MDD); however, this figure differs according to setting and method of identification [10–15]. Our recent systematic review concluded that little is known about rates of depression in people with diabetes in countries outside the UK and USA [16]. Furthermore, any available data specifically in people with Type 2 diabetes have been obtained through different methods to assess depressive symptoms, and so are of limited comparability. Depression or depressive (sub-clinical) symptoms, when occurring in people with Type 2 diabetes, are associated with poor self-care, impaired glycaemic control, poor microvascular and macrovascular outcomes, higher healthcare costs, and compromises quality of life [7–9,17–20]. There are a number of studies that have demonstrated improved outcomes when comorbid diabetes and depression are treated simultaneously in primary care [21,22]. Effective psychological and pharmacological treatments are available, but the under-recognition of depression [23,24] and the stigma attached to mental illness represent major barriers to treatment even in settings where mental health services are well developed. Indeed co-occurring diabetes and depression continues to receive little attention and existing healthcare systems make the management of comorbidity difficult.

Regular screening for depression has been recommended by several professional bodies, however not all countries follow these recommendations, or do not have national or local guidelines for screening for depression in people with Type 2 diabetes. Moreover, the proportion of individuals with diabetes who suffer from clinically significant levels of depressive disorder remains unclear and information on formal approaches to treatment in different countries and care systems is sketchy at best. Our research, the International Prevalence and Treatment of Diabetes and Depression Study (INTERPRET–DD), aims to address these knowledge gaps and investigates the country-specific treatment pathways for individuals with diabetes who receive a diagnosis of depression. At the same time, it will be possible to examine whether the outcomes of diabetes can be improved by better recognition of the presence of depression and its treatment.

INTERPRET–DD currently involves 16 countries (see Fig. 1) and there is a range of treatment experiences between them. As can be seen in Table 1, data pertaining to the

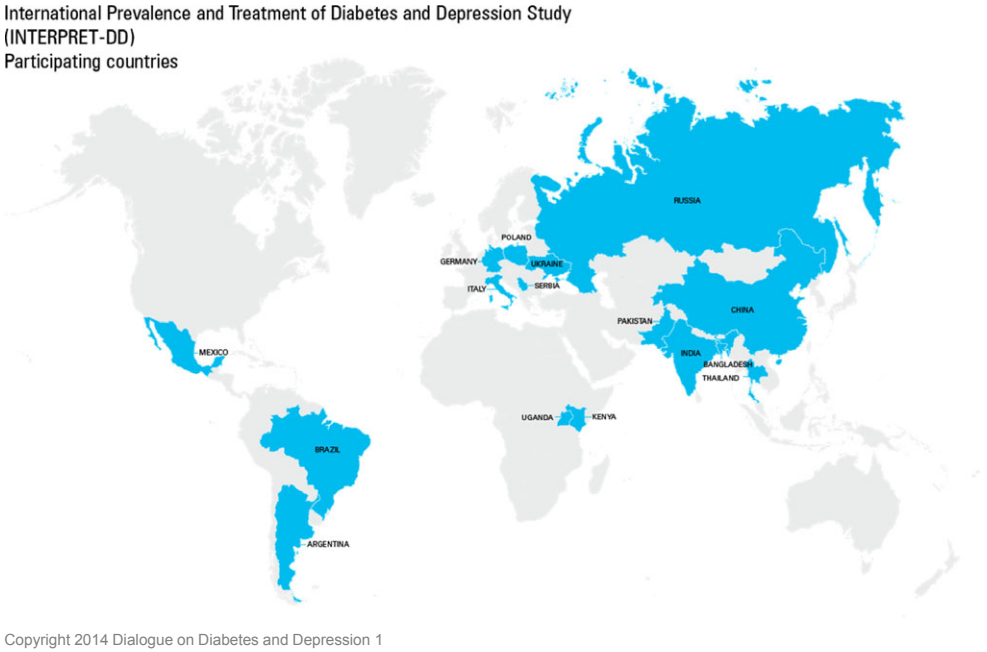

FIGURE 1 Countries participating in the INTERPRET–DD. Copyright © 2014 Dialogue on Diabetes and Depression.

prevalence of comorbid diabetes and depression are lacking in many of the countries involved in INTERPRET–DD, particularly with regard to primary care and the wider diabetes population. Our initial compilation of information has demonstrated that, despite often acknowledging the importance of psychological well-being, the majority of the countries involved in the study do not have formal guidelines, at either the national or local level, which recommend specific ways of identifying and treating individuals with comorbid diabetes and depression (see Table 1). There is also a wide range of methods used and healthcare professionals involved in the process through which depressive symptoms are identified in individuals with diabetes, supporting previous research in this area [21]. However, there is strong agreement in relation to the criteria used for diagnosing clinical depression, with either ICD–10 or DSM–IV commonly used. Pharmacological treatments are most commonly used, however many other therapies are also offered for the care of individuals with depression. Follow-up care also varies, with many of the countries participating in our research reporting no set protocol for the care of people with comorbid diabetes and depression. These data underscore the continued gaps in knowledge with regard to country-specific information, treatment targets and appropriate pathways to care. Our research aims to address this gap, as described below.

The INTERPRET–DD study

In 2007, the Dialogue on Diabetes and Depression (DDD) was established with the over-arching aim of developing a greater understanding of the relationship between these two conditions and to improve the care of individuals with comorbid diabetes and depression (http://diabetesanddepression.org/) [25]. In 2013, under the auspices of the DDD, a new international study was launched with the following objectives agreed at the inaugural meeting of the International Treatment and Prevalence of Diabetes and Depression Study (INTERPRET–DD).

Study objectives

The study has the following objectives:

- to estimate the prevalence and incidence (over 12 months) of depressive disorders and diabetes related emotional distress in adults with Type 2 diabetes attending secondary care facilities;
- to determine how often depression is documented/undocumented in people with Type 2 diabetes attending secondary care facilities and investigate which care pathways are initiated for depression;
- to examine the relationships between Type 2 diabetes, depression, diabetes-related emotional distress, diabetes complications and metabolic control in people with and without depressive disorders attending secondary care in the participating countries;
- to examine the course and impact of treatment of depression, both previously diagnosed (and documented) as well as unrecognized (undocumented) on the course of diabetes, and on patients' emotional well-being;

Table 1 Country-specific data on current treatment pathways for diabetes and depression

	Argentina	Bangladesh	Brazil	China	Germany	India
National guidelines for treatment of comorbid diabetes and depression	No	No	Yes (v)	No	Yes (ix)	No
Estimated prevalence of MDD in Type 2 diabetes (%)						
General population	8.5 (i)	4.6% (iii)	31.9 (vi)	N/K	N/K	N/K
Secondary/tertiary care	34 (ii)	34–36 (iv)	18.8 (vii)	26-38 (viii)	12.6 (x)	23 (xi)
Primary care	N/K	N/K	N/K	N/K	N/K	N/K
Incidence rate of depression in people with Type 2 diabetes	N/K	N/K	N/K	N/K	N/K	N/K
Current referral and treatment procedures						
Health specialties involved in the identification of depression	PSY PCHOL DIAB GP Nurse	PSY GP DIAB	ENDO PSY	DIAB Nurse	PHC/GP DIAB Nurse PSY	PHC/GP
Tools used to screen for symptoms of depression	HAM-D	None‡	None‡	None‡	WHO-5	None‡
Tools used for clinical diagnosis	MINI-5	CL INT	None†	CCMD-3	CL INT	CL INT
Diagnostic criteria for MDD	DSM-IV	DSM IV DSM V	DSM-IV	ICD-10	ICD-10	ICD-10
Current treatment options	PH PTY	MHS PSY PTY ECT CBT	PH PTY	PH PSY	PH PTY light ECT PA OT ART	PH PTY COUNS
Place of referral	PSY	MHS In/outpatient facility	PSY PCHOL	PS	PSY DM/C	PSY PCHOL
Frequency of face-to-face treatment/care	Weekly during acute episode	NSP (average inpatient stay = 29 days) Weekly for group therapy/CBT	NSP	NSP	Weekly (first 4 weeks), 2–4 weeks, Longer intervals after 3 months	NSP
Frequency of follow-up in diabetes department	NSP Preferred option is twice/year with repeat evals	6 weeks for CMD, 6 weeks for CBT treatment	8–12 months for first episode	NSP	3 months depends on diagnosis	NSP (usually weekly)

ART, creative art therapy; CCMD-3, Chinese Classification of Mental Disease; CES-D, Centre for Epidemiological Studies – Depression centre; ENDO, endocrinology; ECT, electroconvulsive therapy; GP, general practitioner/family doctor; HADS, Hospital Anxiety and Depression PH, pharmacology; PHC, primary health care; PCHOL, psychology; PTY, psychotherapy; PSY, psychiatry; PSY-ED, psycho-education.
Numbers in parenthesis refer to the numbered references available on-line only.
*Combined Type 1 + Type 2 diabetes (no data available for Type 2 only).
†Newly diagnosed Type 2 diabetes.
‡No standardized screening instrument used – reliance on patient reports/clinical impression.
§No formal diagnosis using a clinical interview but based on clinical judgement.

Italy	Kenya	Mexico	Pakistan	Poland	Russia	Serbia	Thailand	Uganda	Ukraine
Yes (xii)	No	No	No	Yes (xxi)	No	Yes (xxiii)	No	No	No
4.1-6* (xiii)		N/K	13† (xvii)	N/K	N/K	N/K	N/K	N/K	
27–28 (xiv)		32.7–48.3 (xvi)	43.5 (xix)	N/K	42.5 (xxii)	N/K	30 (xxiv)	N/K	
N/K (xv)	N/K	10.2–28.2 (xvii)	33.3 (xx)	N/K	N/K	N/K	19.2 (xxv)	N/K	N/K
N/K	N/K	N/K	N/K	N/K	N/K	N/K	N/K	N/K	N/K
DIAB GP PCHOL	PHC/GP	DIAB PSY ENDO PHC	DIAB PHC/GP PSY	DIAB GP ENDO	ENDO PSY	ENDO PSY	DIAB	DIAB	DIAB GP ENDO
None‡	HAM-D	PHQ-9	None‡	PHQ-2	CES-D HADS	PHQ-9	PHQ-2	None‡	None‡
CL INT	None§	MINI-5	CL INT	None§	CL INT	MINI-6	CL INT	CL INT	None†
ICD-10 DSM-IV	DSM-V	DSM-V ICD-10	ICD-10	ICD-10	ICD-10	ICD-10	ICD-10 DSM-IV	ICD-10	DSM-V
PH PTY MHS PCHOL	PH PTY(if referred to PSY)	PH PTY/ CBT	PH CBT	PH PTY COUNS CBT	PH	PH PTY	PH PTY CBT PSY-ED	PH PTY	PH
GP MHS	PSY (if PHC cannot treat)	MHS PSY	PSY	PSY	PSY	PSY	PSY	PSY	PSY
1–2 weeks (acute phase) monthly later on	NSP	Week (acute phase) 1–3 months	8 wks	Monthly at start of PH Weekly if COUNS	NSP	Weekly/ 8 weeks for CBT	NSP	NSP (but meds usually used for 8–12 weeks	NSP
6–12 months	NSP (usually during diabetes care)	NSP (none in diabetes care)	2 weeks, then 1 month	NSP	NSP (but rarely followed up)	N/K	NSP	NSP (but clinics take place weekly)	NSP

Scale; CL INT, clinical interview; CMD, common mental disorders; COUNS, counselling; DIAB, diabetology; DM/C, cservice at the diabetes Scale; MHS, mental health service; NSP, no set protocol; N/K, Not known; OT, occupational therapy; PA, physical activity/exercise therapy;

Table 2 Inclusion and exclusion criteria for the INTERPRET-DD study

Exclusion criteria	Inclusion criteria
Duration of diabetes < 12 months	Adults 18-65 years of age with type 2 diabetes*
Communication or cognitive difficulties or inability to complete the survey tools	Duration of diabetes > 12 months before the point of contact
Any life-threatening or unstablized serious condition (e.g. Cancer, stroke) in last 6 months or where patient has not fully recovered/has more than minor effects from a stroke)	Attending their diabetes out-patients (secondary care) facilities
Inpatients (unless admitted for diabetes self-management)	
Planned hospital admission for a medical intervention in the next 3 months	
Dementia, Parkinson's disease, epilepsy or other serious neurological condition	
Clinical diagnosis of dependency on alcohol or other substance (not tobacco)	
Current/within last 3 months participation in other studies (except observational studies)	
Living outside the diabetes clinic catchment area/unlikely to be available for follow-up	
Currently pregnant/ pregnant/had a child in the last 6 months	
Diagnosis of schizophrenia	

*The WHO criteria are used to define Type 2 diabetes: random plasma glucose ≥ 11.1 mmol/l or fasting plasma glucose ≥ 7.0 mmol/l or 2–hour plasma glucose ≥ 11.1 mmol/l

- to assess the specificity and sensitivity of two depression screening instruments (the PHQ–9 and the WHO–5) when used in people with Type 2 diabetes; to compare the collected data among countries applying the same protocol.

A further, secondary objective is to create the first worldwide network of people researching the experience, treatment and care of those with comorbid diabetes and depression.

Methods

The INTERPRET–DD study will take place over a 2-year period with data collection at two points 1 year apart, as described in Fig. 2. Inclusion/exclusion criteria are shown in Table 2. Each centre will recruit 200 people with Type 2 diabetes attending their diabetes secondary care facility. Type 2 diabetes is defined according to WHO criteria (random plasma glucose ≥ 11.1 mmol/l or fasting plasma glucose ≥ 7.0 mmol/l or 2–hour plasma glucose ≥ 11.1 mmol/l). Ethics approval was obtained both from the Open University Research Ethics Committee and from each country's local ethics committee.

Every participant will undergo a psychiatric interview on entry to the study, after completing two depression-screening instruments: the PHQ–9 [26,27] and the Well-Being Index (WHO–5) [28,29]. The PHQ–9 consists of nine items on a four-point Likert-type scale. It has good sensitivity and specificity with regard to identifying cases of depression as well as being sensitive to change over time, and it has been used in a number of different countries [26,27,30,31]. Using the PHQ–9 will allow us to test both the sensitivity and specificity of this instrument in the different countries. Furthermore, it will provide us with an opportunity to examine the level of depressive symptoms on entry to the study and how they relate to subsequent symptoms (at 1-year follow-up) and any care-seeking behaviour at both the sub-clinical and clinical diagnosis level.

The WHO–5 is a well-validated measure widely used in a range of settings and has good sensitivity to depressive symptoms [28,29]. By using these two different scales it will be possible to determine whether one or other more closely approximates clinically significant levels of depressive disorder.

It is important to distinguish between depressive symptoms and emotional distress related to having diabetes as this may inform treatment decisions [32]. To our knowledge, those with high levels of diabetes-related emotional distress are rarely identified in practice and only then if they report clinically significant symptoms of depression. A combination of screening for depression alongside monitoring of diabetes-related emotional distress during routine clinical care could optimize patient well-being and quality of life. Through our observations of current clinical practice over time we hope to be able to illuminate these issues and provide the much needed information on the impact of diabetes distress, and whether help is sought, in order to be able to provide recommendations on the most appropriate advice for people seeking help in managing this. In order to address this important issue, participants will also be asked to complete the 20-item Problem Areas in Diabetes (PAID) scale, which is a measure of diabetes-related emotional distress [33]. All questionnaires will be

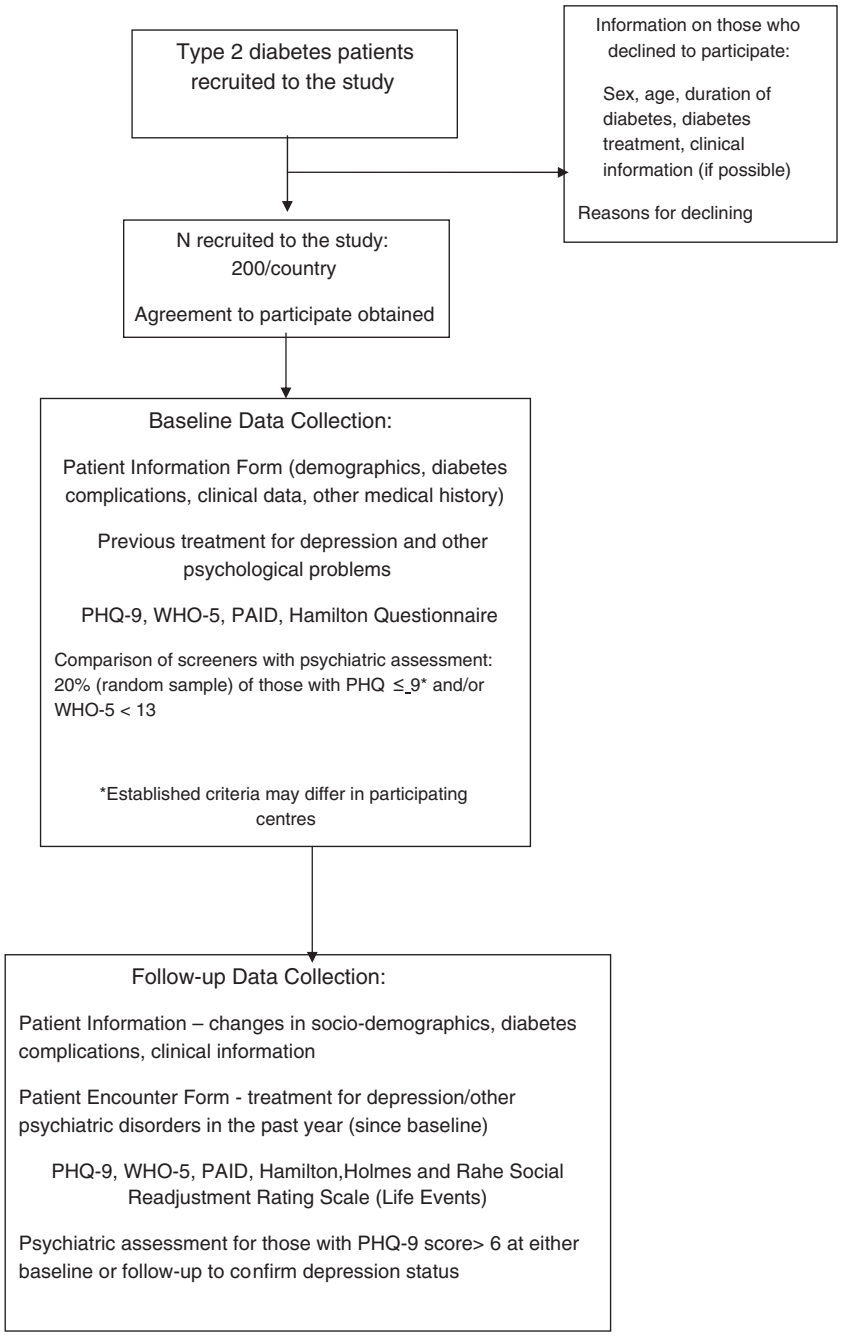

FIGURE 2 Flow of participants through the study.

completed using standard self-complete methods in the appropriate language, or assisted one-to-one collection, with the questions read out by the researcher and answered by the participant. Where no existing translation/cultural adaption of the questionnaires was available they were adapted using standard forward/back-translation procedures. In addition, each country's investigators ensured they were culturally applicable through their development over several iterative stages involving discussion and testing with a range of healthcare professionals and people with Type 2 diabetes, focusing on the meaning of terms as well as language.

In order to examine the relationship between depressive symptomatology and clinically significant depression, a psychiatric interview will then be conducted by a trained psychiatrist using the MINI International Neuropsychiatric Interview (MINI) [34]. The MINI, which takes between 15 and 40 minutes to administer, has been widely used in a range of different populations (including those with serious illness and in community surveys) and is a reliable diagnostic tool

even when used by non-psychiatrists, as long as appropriate training is given [34]. Individuals diagnosed with depression (or other psychiatric disorders such as anxiety disorders) will be advised to consult their physician for further assessment and treatment. If any individual indicates suicidality (question 9 on the PHQ–9) the psychiatrist conducting the clinical interview will initiate appropriate care.

Full clinical and demographic data are collected for each participant on entry to the study and again at follow-up after 1 year, through the examination of medical records and patient interview. Data include any documented diagnosis of depression or other mental health problem, socio-economic information, smoking history, blood glucose, blood pressure and cholesterol levels, BMI, physical activity (self-reported frequency and type), medications and diagnosed diabetes complications (retinopathy, cardiovascular disease, diabetic neuropathy and nephropathy). We will thus be able to compare those who are diagnosed with depression and those who are not given such a diagnosis in terms of these factors (although we recognize that a 1-year follow-up may not be long enough to examine the relationship between depression and diabetes complications). In addition, each participant is asked a series of questions regarding whether they have experienced or if any healthcare professional has ever told them they have depression or other mental health problem (as this may not have been documented) as well as each diabetic complication (heart disease, etc.). We feel this is important as personal knowledge of their health status may have an impact on their mental health or emotional well-being.

Follow-up data collection

After 12 months, along with repeated measurements (see Fig. 1), a detailed systematic collection of patient treatment pathways data, using the WHO Patient Encounter Form (PEF) devised by Gater and colleagues [35] will also be conducted. The PEF has been used successfully in a number of countries in studies of care pathways for psychiatric patients [35]. It forms a record of information regarding the process, content and outcome of consultations for mental disorders and will be completed with the patient by the psychiatrist conducting the psychiatric interview. In order to assist with the interpretation of this data, and as a marker for the individual patient's intrinsic motivation for engaging in treatment, the PEF includes questions on who instigated the request for treatment or care for any mental health problem. All forms of treatment that the patient engages in during the follow-up period will be recorded, including for example medication, cognitive behavioural therapy and psychotherapy, but also self-help remedies and relaxation therapies. Both qualitative and quantitative data will be collected, with the descriptions of the particular problems presented at each consultation forming the basis for the qualitative data analysis.

Information on national, regional and centre based existing care pathways will also be systematically gathered in order to complement the PEF data, including the availability of talking therapies and pharmacological treatments.

Statistical analysis

Our data are being collated and will be analysed in the UK with all 16 countries supplying their data to the project lead. Previously published data have indicated that the lowest rate of major depressive episode (MDE) is in Germany with a prevalence of 12.6%. Based on this, at a power of 80%, a sample size of 112 would be required for this study. The highest prevalence rates of MDE have been found in Pakistan (43.5%) and, at 80% power, a sample size of 184 would be required. Our subsequent pilot study data has indicated an overall mean prevalence of 14%, which at 90% power would indicate a sample size of 179 would be needed.

Our calculations have demonstrated that we will have greater power (using the highest prevalence rate in Pakistan of 43.5% at 95% power a sample size of 403 is needed) when we combine the data from all countries (3200 participants). This number of study participants will give sufficient power to the study to be able to investigate the combined prevalence of depressive disorder and to examine differences according to duration of diabetes, age, sex and other important variables.

Our plans for data analysis include both univariate and multivariate statistical analyses. We expect to be able to estimate the number of patients with Type 2 diabetes who have previously undocumented depression as well as some incidence data after follow-up. Descriptive analyses will concentrate on the overall patient group across all centres, with further analyses to compare centres. An overall estimate of the case comorbidity proportion for patients with Type 2 diabetes plus comorbid depression will be made. For individual centres, case comorbidity proportions will be estimated and the differences compared. Baseline data regarding the clinical characteristics and known risk factors (hypertension, HbA_{1c}, etc.) will be compared between people with and without comorbid depression. To allow for potential confounding effects, a combination of linear and logistic regression modelling will be used. The potential clustering effects of centre will be investigated, using multiple linear regression and where appropriate multi-level mixed models. To investigate the role of undiagnosed depression, further analyses comparing three groups of patients will be undertaken; Type 2 diabetes only, Type 2 diabetes + known depression, Type 2 diabetes + newly detected depression. Main follow-up analyses will be to evaluate changes over the 1-year study period with respect to Type 2 diabetes and depression and associations with other diabetes related factors. Pathways to care and treatment patterns will also be examined and compared between different countries. A combination of multiple

linear and logistic regression modelling techniques and mixed multi-level modelling will be used to investigate the importance of factors and to adjust for potentially confounding and centre related clustering effects. The results of the two screening tests to identify depressive symptoms will be compared to the MINI depression diagnostic results for each patient allowing the determination of overall sensitivity and specificity for both instruments using both the whole sample and each individual country. This will permit us to investigate and report centre specific sensitivities and specificities.

We will also be examining whether the factor structure of each questionnaire is invariant across samples using multigroup confirmatory factor analysis – this will help us understand whether there are differences in interpretation of the questions in each questionnaire between countries.

Our qualitative analyses will further illuminate the different countries' treatment pathways and patients' experiences of treatment. The qualitative information (i.e. the description of particular problems presented) will be coded and common themes identified.

Although this study cannot identify the proportion of people with diabetes who have unrecognized depression in the general population, our study design does allow for a close examination of current practice in the participating centres, which will help us identify successful referral and treatment processes that will inform care more widely. Sixteen countries are in the process of collecting data but a further eight have expressed interest in joining our study, including Canada, Vietnam, Kuwait and Ethiopia. The countries involved in our study have a range of different models of care, both in terms of the organization of services and the treatment pathways available. To ensure we obtain expertise from service providers caring for people with diabetes and/or psychiatric/psychological problems each site is led by both a diabetologist or endocrinologist and a psychiatrist. Secondary care facilities (rather than primary care services which are not developed in some countries) have been chosen as the focus for data collection as these are the most common feature of diabetes care between all the countries involved in the study. Moreover, the facilities where recruitment is taking place are recognized as providing a high quality of care, where medical records are routinely kept. Our pilot study has demonstrated it is possible to obtain and record a range of medical data on each participant to be entered systematically into our standardized data collection tool so as to ensure comparability across the countries. Over the past 6 months all the pilot studies have been successfully carried out in the first 16 countries that have joined the INTERPRET–DD study. This work has demonstrated that the survey instruments are easy to use without any concerns being expressed by either the participants or researchers, and that the agreed protocol is a viable one that can be implemented in all the study settings.

Conclusions

The INTERPRET–DD study provides a unique opportunity to investigate the relationship between diabetes and depression across the globe. It is the first study of its kind to focus on these comorbid conditions and brings with it future opportunities to collaborate and share data. Through our research, we will produce appropriate screening and assessment instruments and create the world's largest network of centres collaborating in the effort to address the problem of comorbidity and identify the most beneficial ways of treating depression in people with diabetes.

By examining between-country variations we will be able to identify the gaps and commonalities in successful treatment and care, leading to recommendations for both future research (for example, randomized controlled trials) and practice.

Our study will increase the understanding of the impact of comorbid diabetes and depression and identify the most appropriate (country-specific) pathways via which patients receive their care. This research will lead to recommendations for best practice with regard to the identification and treatment of people with comorbid diabetes and depression relevant to the different participating centres. This will mean that our findings are directly and easily transferable to other similar care settings in each of the participating countries and can inform the development of both primary and specialized health services. A huge gain for both individuals and for public health would accrue if comorbid diabetes and depression were treated effectively.

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Competing interests

L. Cimino provides services to the Association for the Improvement of Mental Health Programmes on a retainer basis. He serves on the Executive Committee of the Board of Directors of the World Federation for Mental Health and chairs the Board of Directors of the Indiana Centre for Intercultural Communications.

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Supporting Information

Additional Supporting Information may be found in the online version of this article:

Table S1. References.