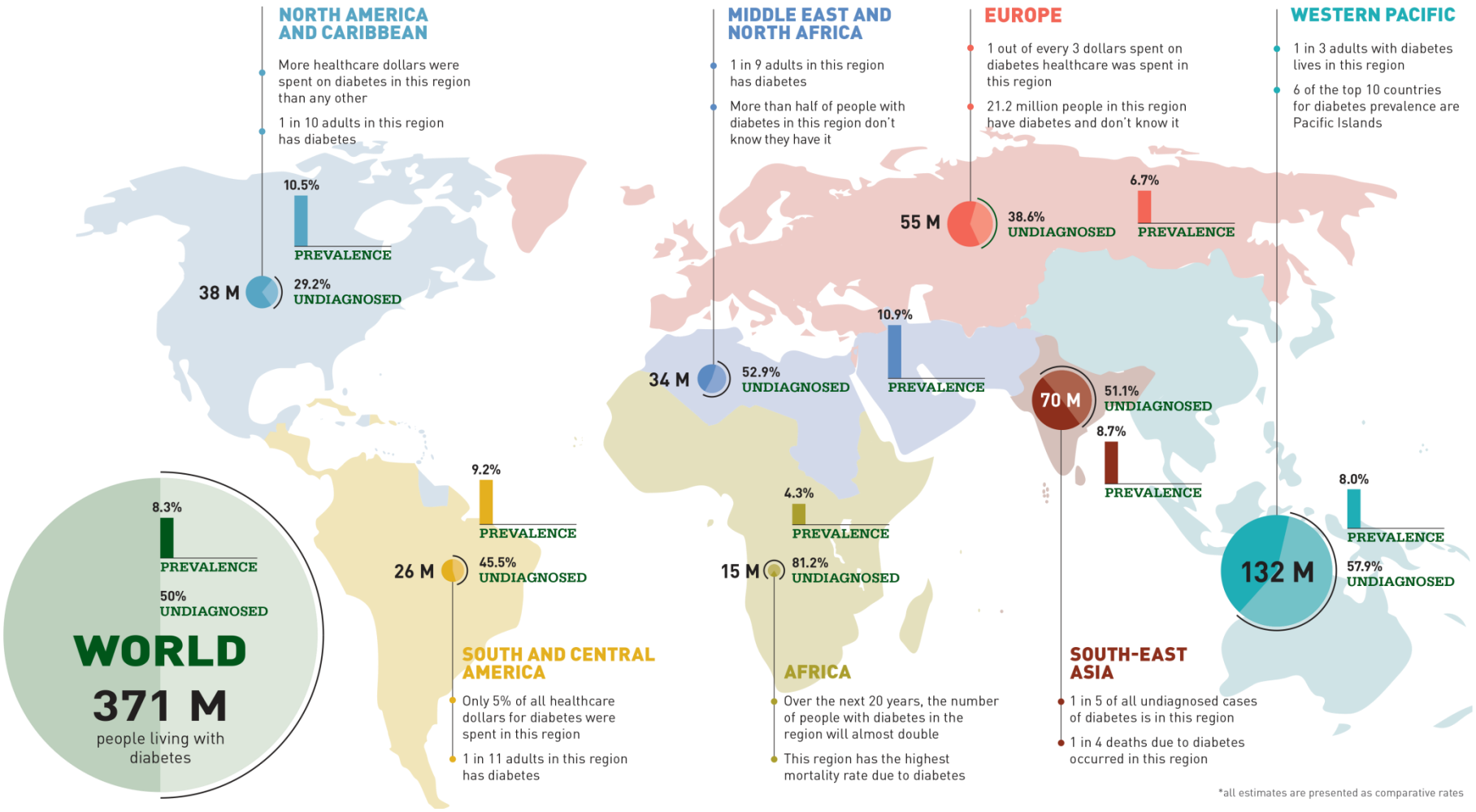
Beyond blood glucose / The Diabetes Health Profile – Measuring the patients perspective of the benefits of diabetes interventions

Dr Keith Meadows
DHP Research & Consultancy Ltd

Global Diabetes impact



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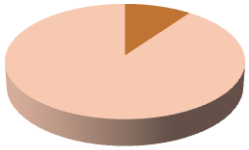
Diabetes in the U.K.

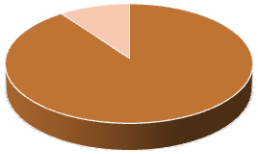
UK Diagnosed

2.9 million
diagnosed with diabetes by 2011

Diabetes type



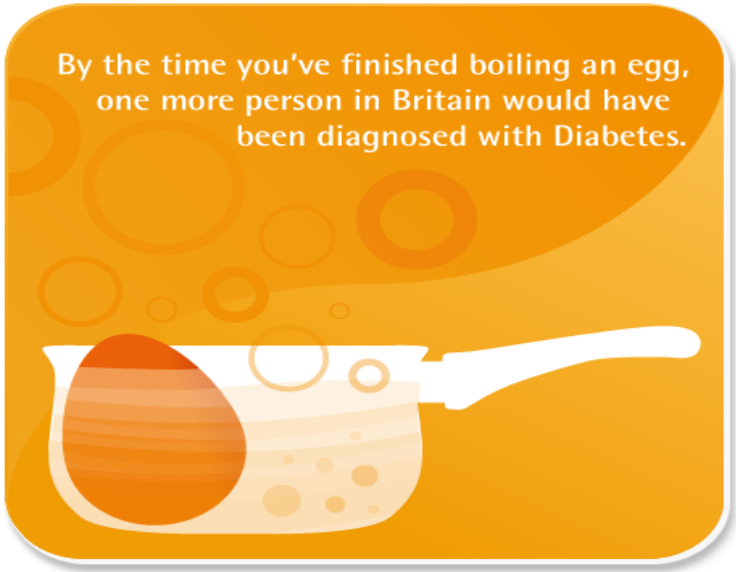
10% of people with diabetes have Type 1



90% of people with diabetes have Type 2

Financial costs

£192 million a week spent by the NHS



The impact

52%	Deaths due to cardiovascular disease
21%	Type 1 Deaths due to kidney disease
70%	Of people die within 5 years of an amputation

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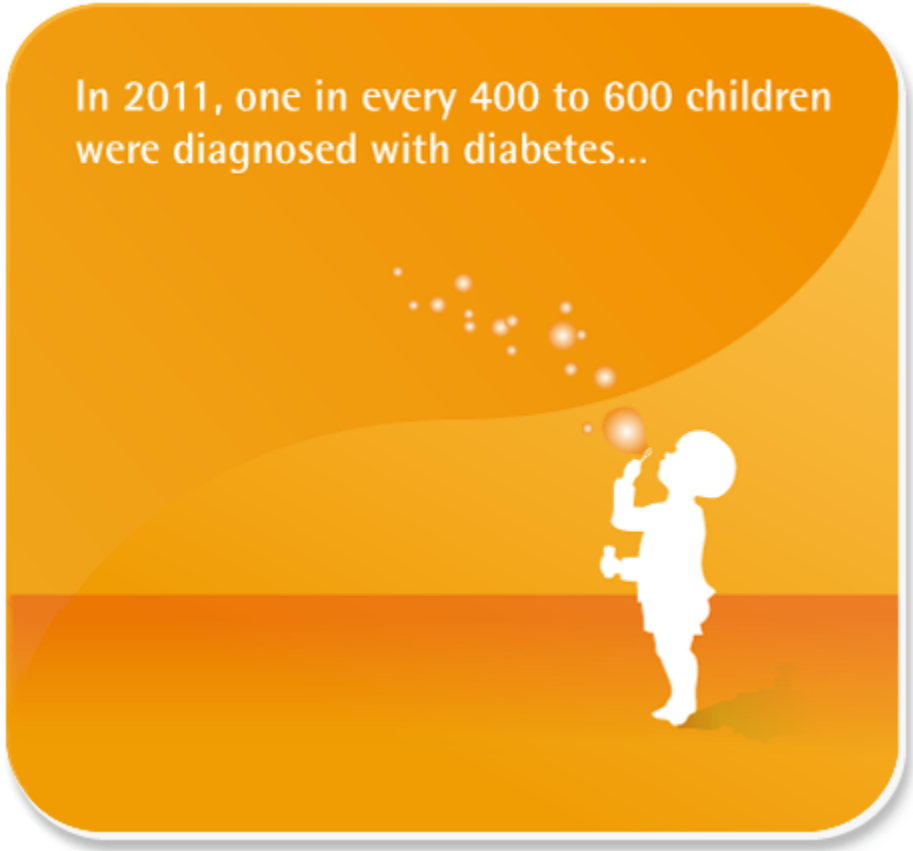
Diabetes in the U.K.



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The Psychological Impact of Living with Diabetes

The facts

10%

of the population in Britain have depression at any one time

However,

according to Diabetes UK, people with diabetes are **twice** as likely to experience depression...

...and the risk is higher for women than for man

"Yet there is little routine psychological support for people with diabetes."

Diabetes UK

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The Psychological Impact of Living with Diabetes

ANXIETY

aggression

Denial

Eating problems

Treatment non-adherence

POOR QUALITY OF LIFE

disruption to social and professional life

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Diabetes-specific PROs in a Real World Setting

- Efficacy of treatment
- Need for real world data driven by changing regulatory environment, drug safety and efficacy
- Identification of factors leading to treatment non-adherence and drug ineffectiveness
- Enables clinicians to tailor treatment regimens based on patient needs
- Increase treatment adherence as part of patient support programmes

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The Diabetes Health Profile

The Diabetes Health Profile (DHP),

a multidimensional, diabetes-specific (T1 and T2), patient self-report outcome measure of the psychological and behavioural impact of patients living with diabetes.

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Provisional development of the DHP

- A review of the literature.
- In-depth interviews with 45 diabetes patients analysed using a thematic approach.
- Examination of existing instruments of psychosocial functioning.
- Discussions with health care professionals (diabetologists), Diabetes Specialist Nurse (DSN) and dieticians.

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The Diabetes Health Profile

The conceptual model

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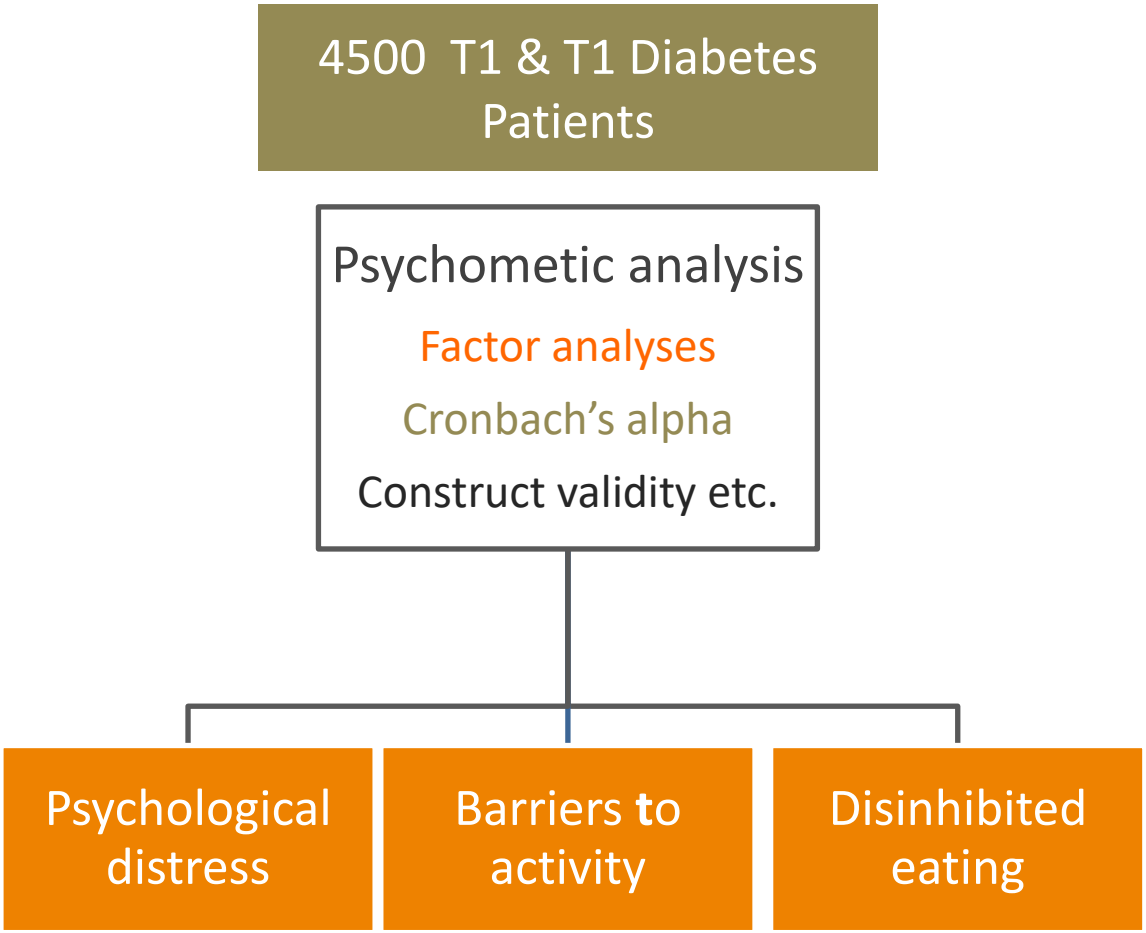
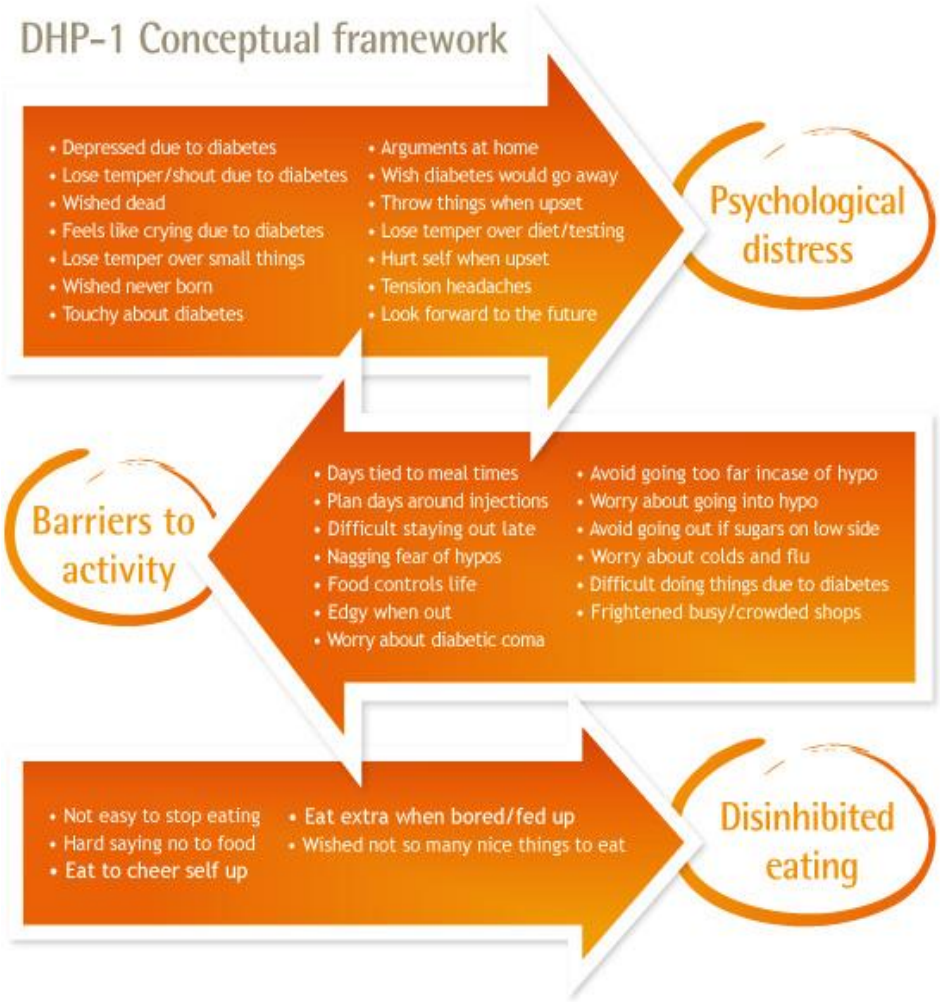
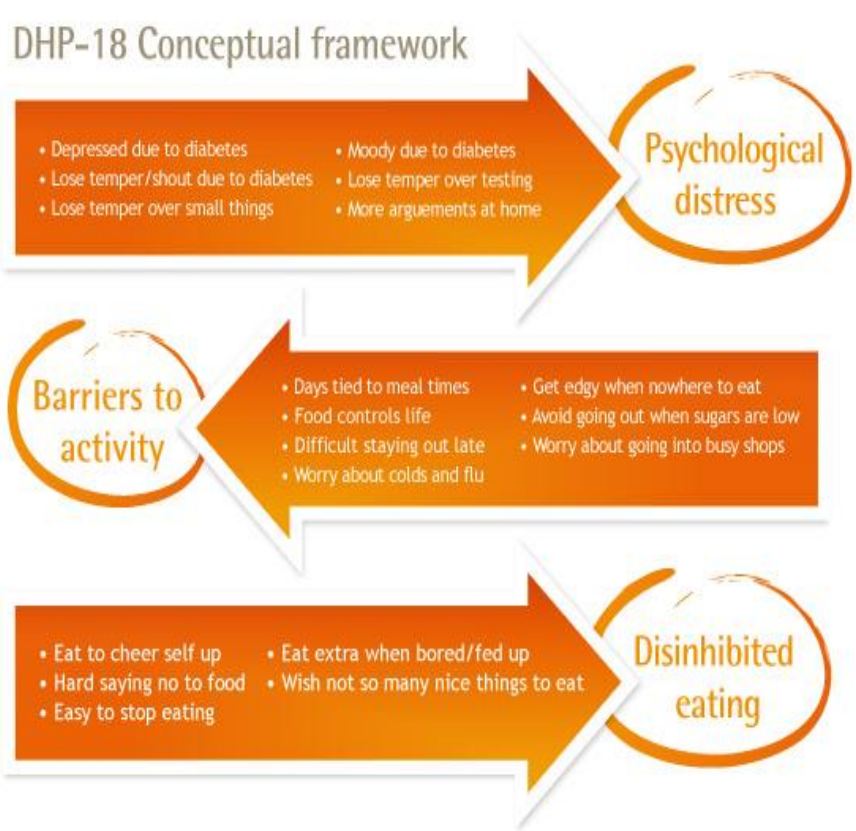
Provisional development of the DHP



Conceptual Framework for the DHP-1 and DHP-18





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The Diabetes Health Profile (DHP)

	DHP-1	DHP-18
Administer	Type 1 Diabetes Individuals 16 years and older	Type 1 Diabetes Individuals 16 years and older
Reading Level	6th grade	6th grade
Scales (No of items)	Psychological distress (14) Barriers to activity (13) Disinhibited eating (5)	Psychological distress (6) Barriers to activity (7) Disinhibited eating (5)
Response options	Four-point adjectival scales	Four-point adjectival scales
Formats	Paper-and-pencil, interview	Paper-and-pencil interview, electronic hand held, tablet, IVR, web
Scoring	Items scores 0-3 in each dimension summed & transformed to produce score 0 (no dysfunction to 100)	Items scores 0-3 in each dimension summed & transformed to produce score 0 (no dysfunction to 100)
Completion time	9–12 minutes	5–6 minutes
Research & Resources	DHP manual, research support, training and workshops*	DHP manual, research support, training and workshops**
FAQs	Yes (see below)	Yes (see below)

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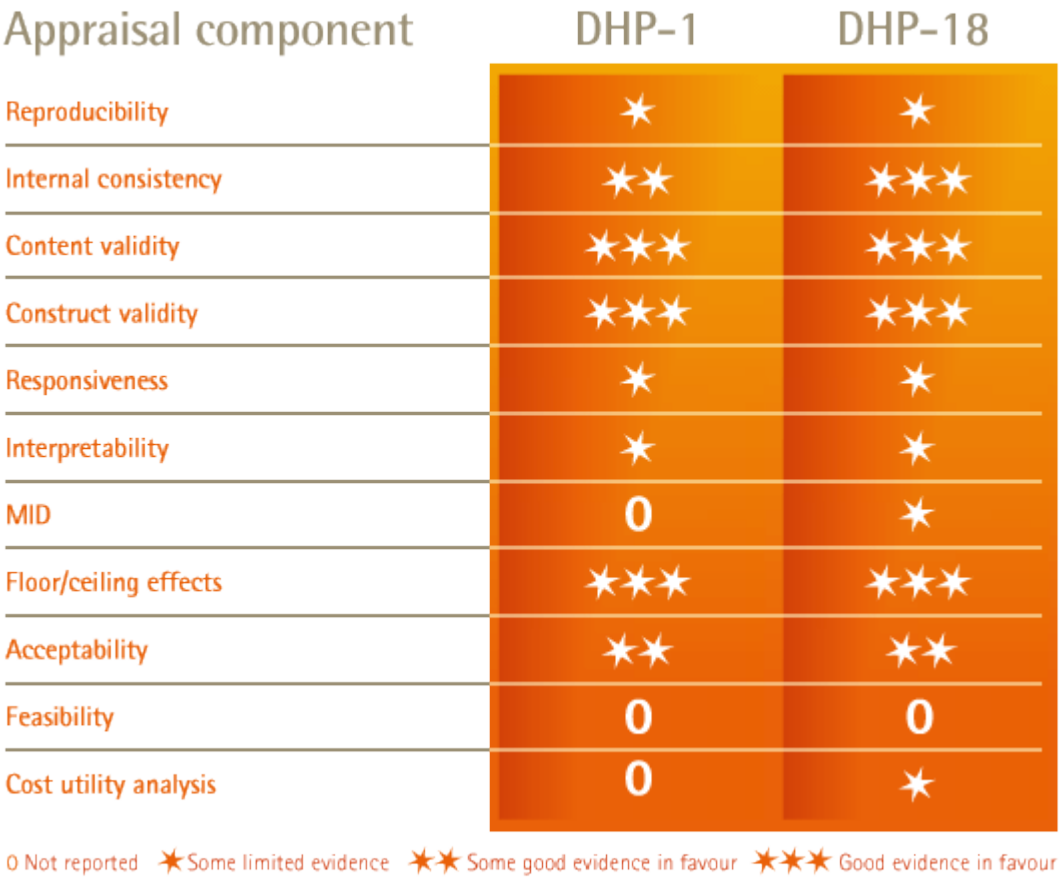
Development of the Diabetes Health Profile



Appraisal component	DHP-1	DHP-18
Reproducibility	★	★
Internal consistency	★★	★★★
Content validity	★★★	★★★
Construct validity	★★★	★★★
Responsiveness	★	★
Interpretability	★	★
MID	0	★
Floor/ceiling effects	★★★	★★★
Acceptability	★★	★★
Feasibility	0	0
Cost utility analysis	0	★

0 Not reported ★ Some limited evidence ★★ Some good evidence in favour ★★★ Good evidence in favour

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Previous and Current Users of the DHP

More than

12,000

Type 1 & Type 2

Respondents

Have completed the

DHP-1 / DHP-18

Instituts thématiques Inserm
Institut national de la santé et de la recherche médicale

GIG CYMRU NHS WALES
Bwrdd Iechyd Prifysgol Abertawe Bro Morgannwg University Health Board

Lilly DIABETES

novo nordisk

CHU GRENOBLE

UCL

DiabetesTools HEALTH BY KNOWLEDGE

Centre Hospitalier Régional Universitaire de Lille

UMC Universitair Medisch Centrum Utrecht

gsk GlaxoSmithKline

SANOFI

NUS National University of Singapore

DH Department of Health

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Typical Applications of the DHP

- Measure improvement or decline in the psychological and behavioural functioning of patients
- Screen for unmet need
- Demonstrate drug efficacy
- Assess treatment effectiveness
- Assess intervention programmes
- Enhance treatment adherence by improving communication between you and your patients

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Translations

- Bulgarian
- Croatian
- Czech
- Danish
- Dutch
- Dutch (Belgium)
- English (Canada)
- English (USA)
- Finish
- French
- French (Belgium)
- French (Canada)
- French (Swiss)
- German
- German (Austria)
- German (Swiss)
- Hungarian
- Italian
- Italian (Swiss)
- Mandarin
- Norwegian
- Polish
- Romanian
- Turkish (German)
- Slovak
- Slovenian
- Spanish
- Spanish (USA)
- Swedish

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Modes of Administration

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User Guide: DHP-1 & DHP-18

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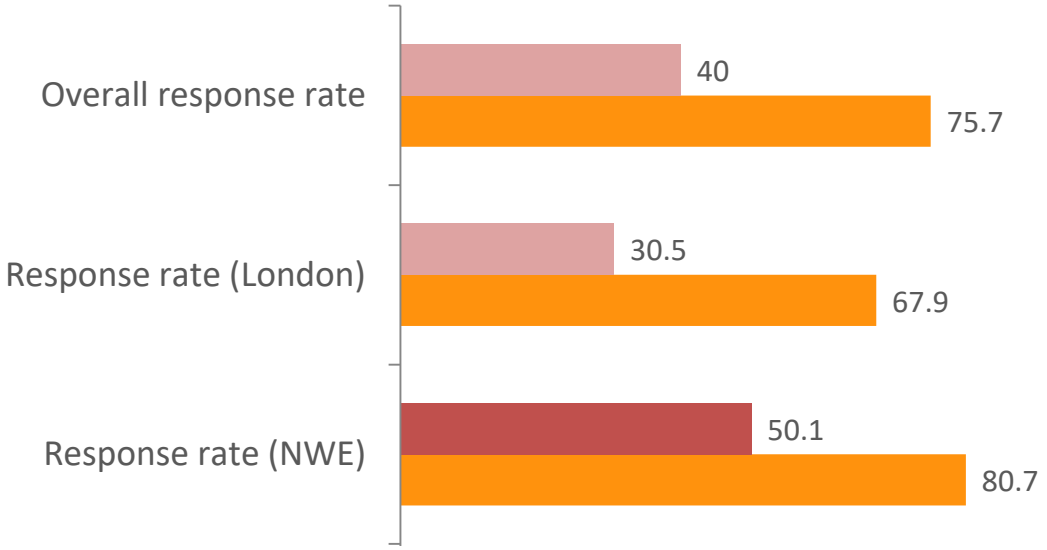
DHP Response Rates and Data quality

Pilot study of patient reported outcome measures (PROMs) in primary care

UK Department of Health

DHP-18 % Response Rates

33 General practices 1121 Questionnaires (Baseline)
424 Questionnaires (Follow-up)



Pilot study of patient reported outcome measures (PROMs) in primary care. *Report to the Department of Health.* Michele Peters Department of Public Health University of Oxford 2013.

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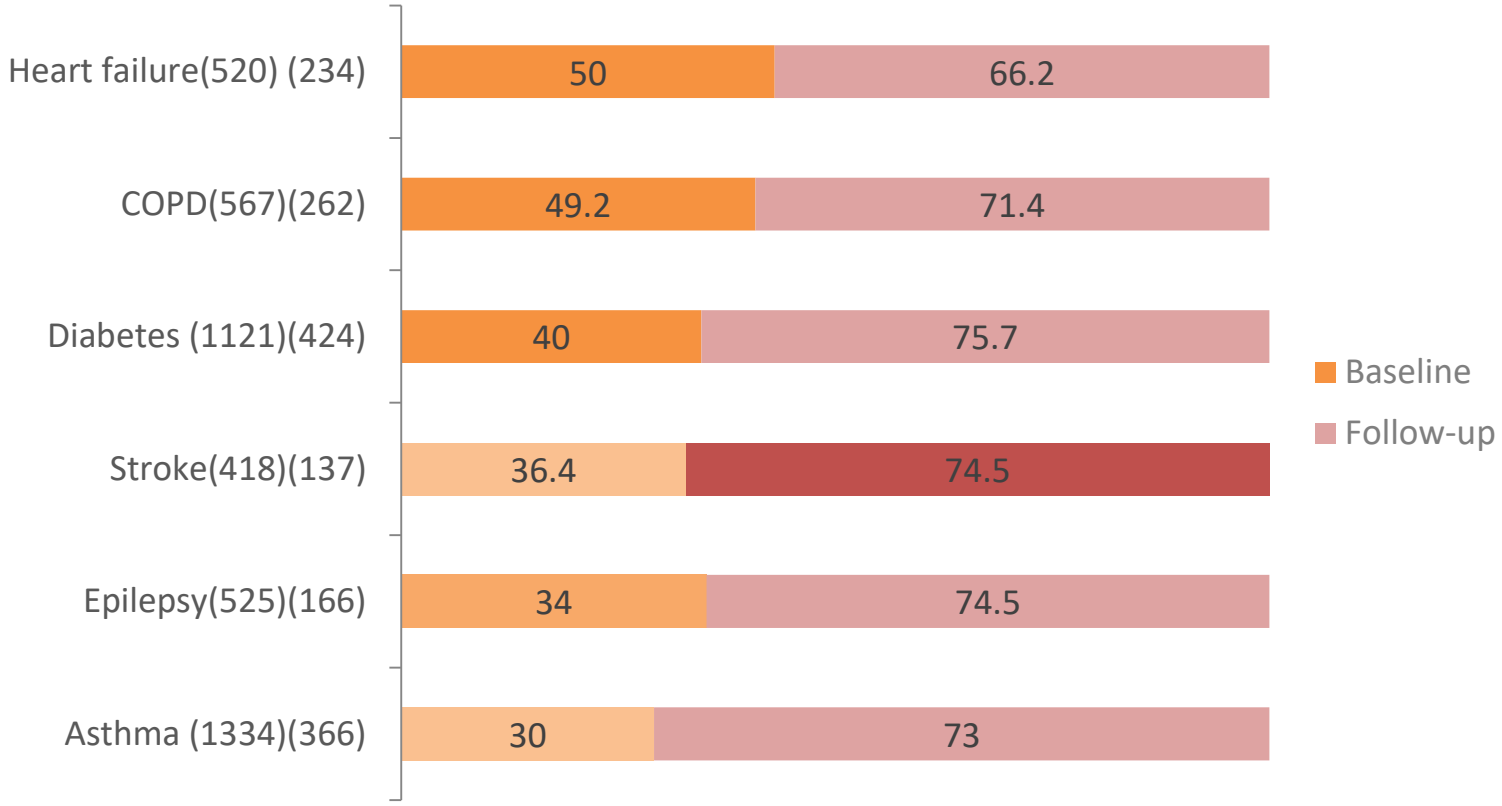
Response rates by LTC



Pilot study of patient reported outcome measures (PROMs) in primary care. *Report to the Department of Health.* Michele Peters Department of Public Health University of Oxford 2013.

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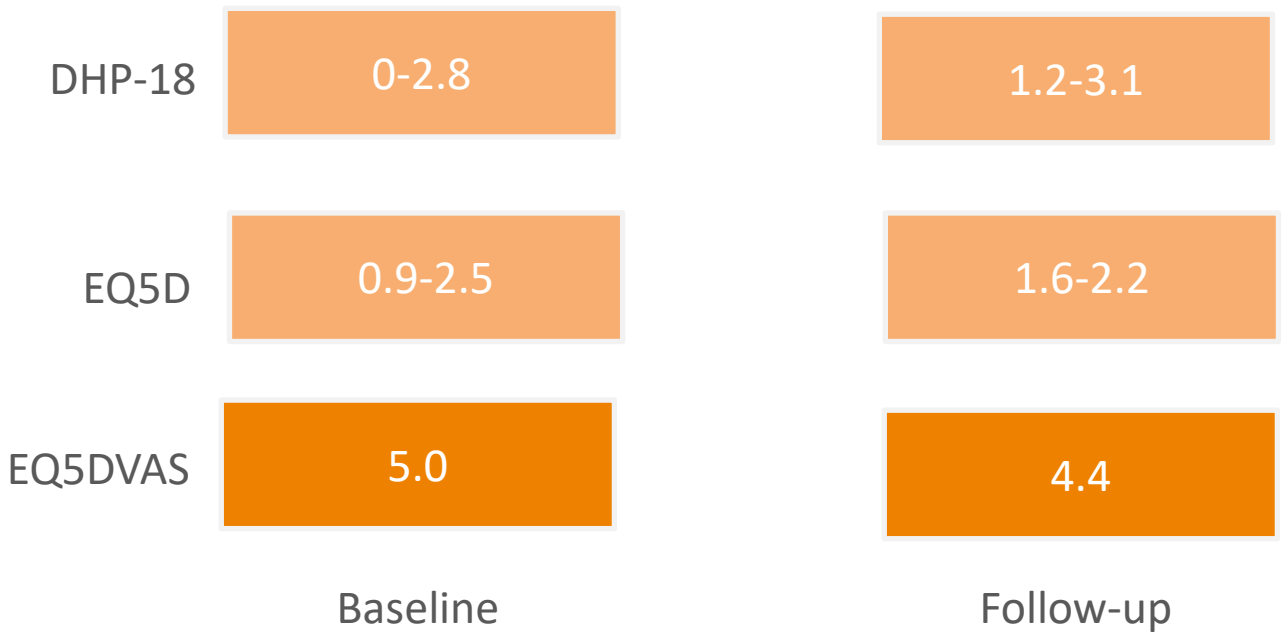
% of missing data for the EQ5D and DHP



Pilot study of patient reported outcome measures (PROMs) in primary care. *Report to the Department of Health.* Michele Peters Department of Public Health University of Oxford 2013.

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What does the Diabetes Health Profile tell us about living with diabetes?

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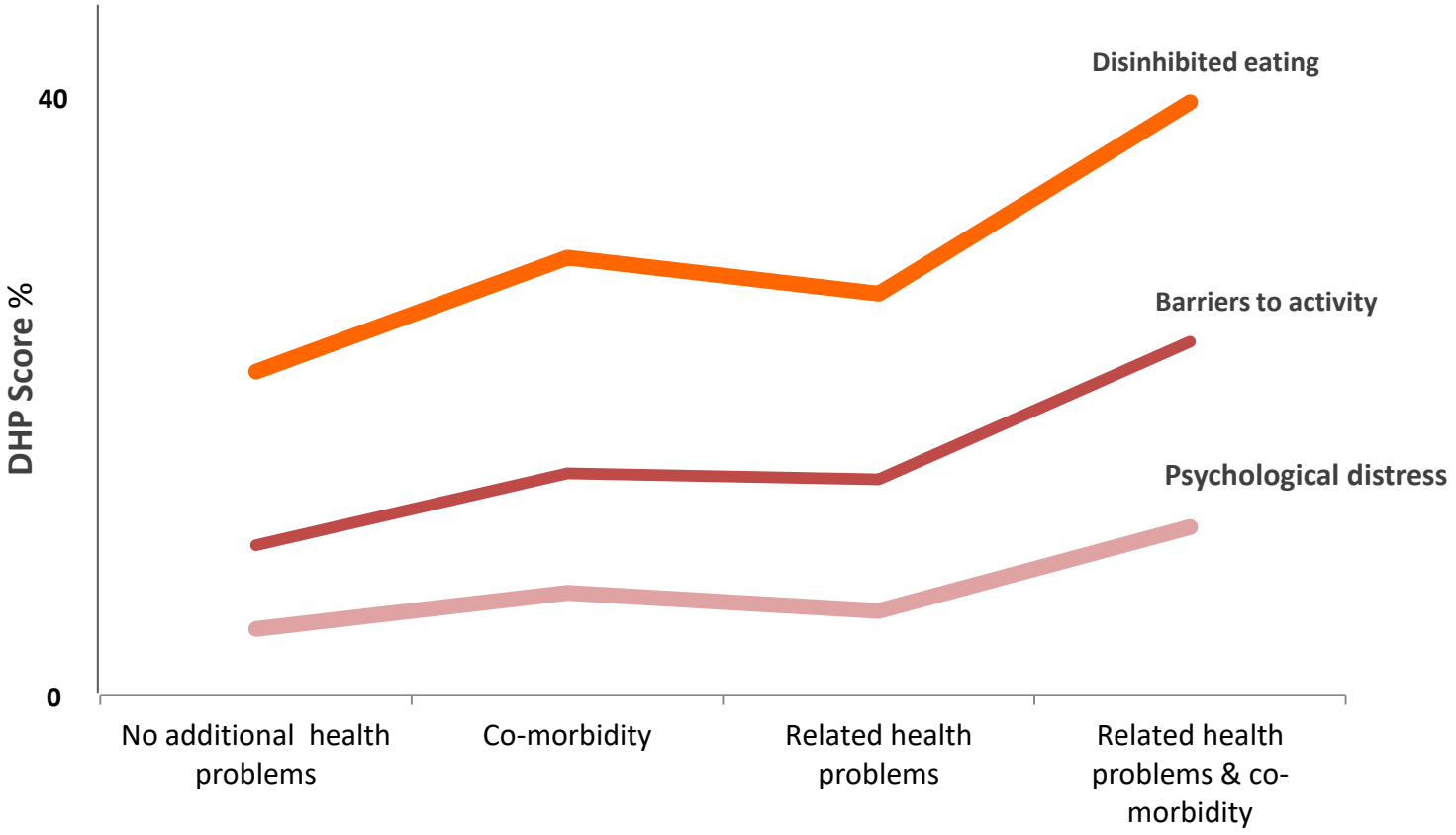
DHP-18 Domain scores by comorbidity

N=1802 (45% RR) TI & T2 diabetes general practice patients



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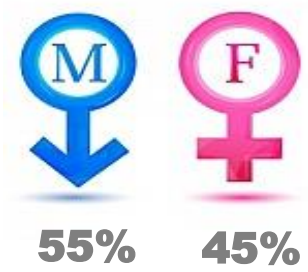
Living with diabetes - Interpreting the DIABETES HEALTH PROFILE (DHP)

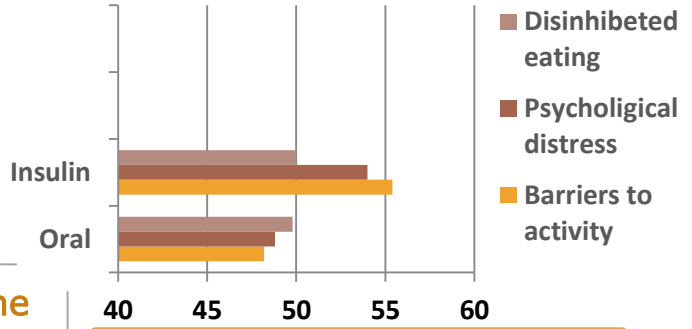
91% Type 2 and 9% Type 1 patients completed the questionnaire.



Mean age

63.9 years

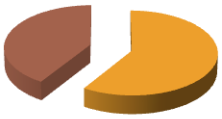
DHP domain scores by treatment modality



Score 0=No dysfunctioning p<0.05

77%

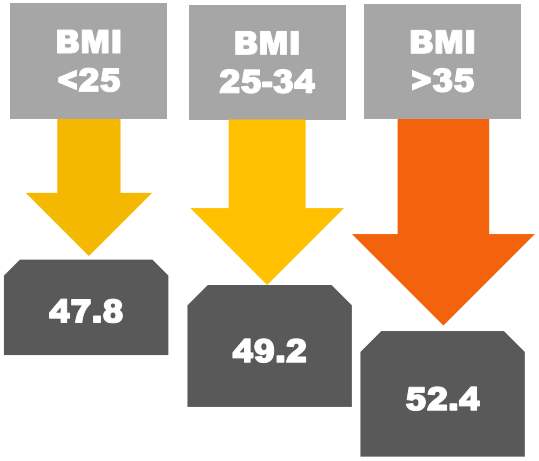
Of patients experiencing three severe hypoglycaemic episodes reported their days are tied to meal times.



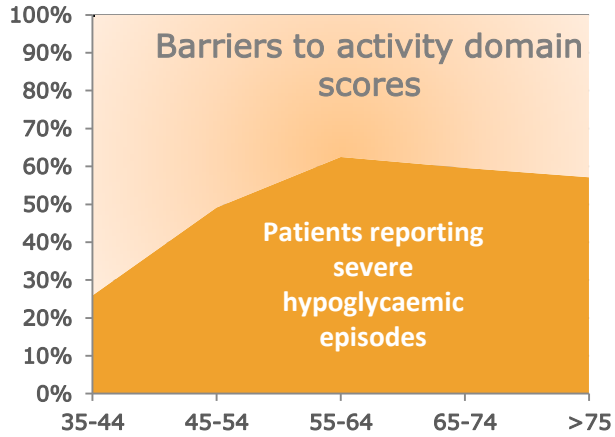
59%

Of patients experiencing one severe hypoglycaemic episode reported their days are tied to meal times.

Patients (mean) scores on the Disinhibited eating domain by BMI



Score 0=No dysfunctioning p<0.05



Score 0=No dysfunctioning

Factors associated with psychological and behavioural functioning in people with type 2 diabetes living in France.Stephanie Boini, Marie-Line Erpelding et al.Health Quality of Life Outcomes 2010, 8:124

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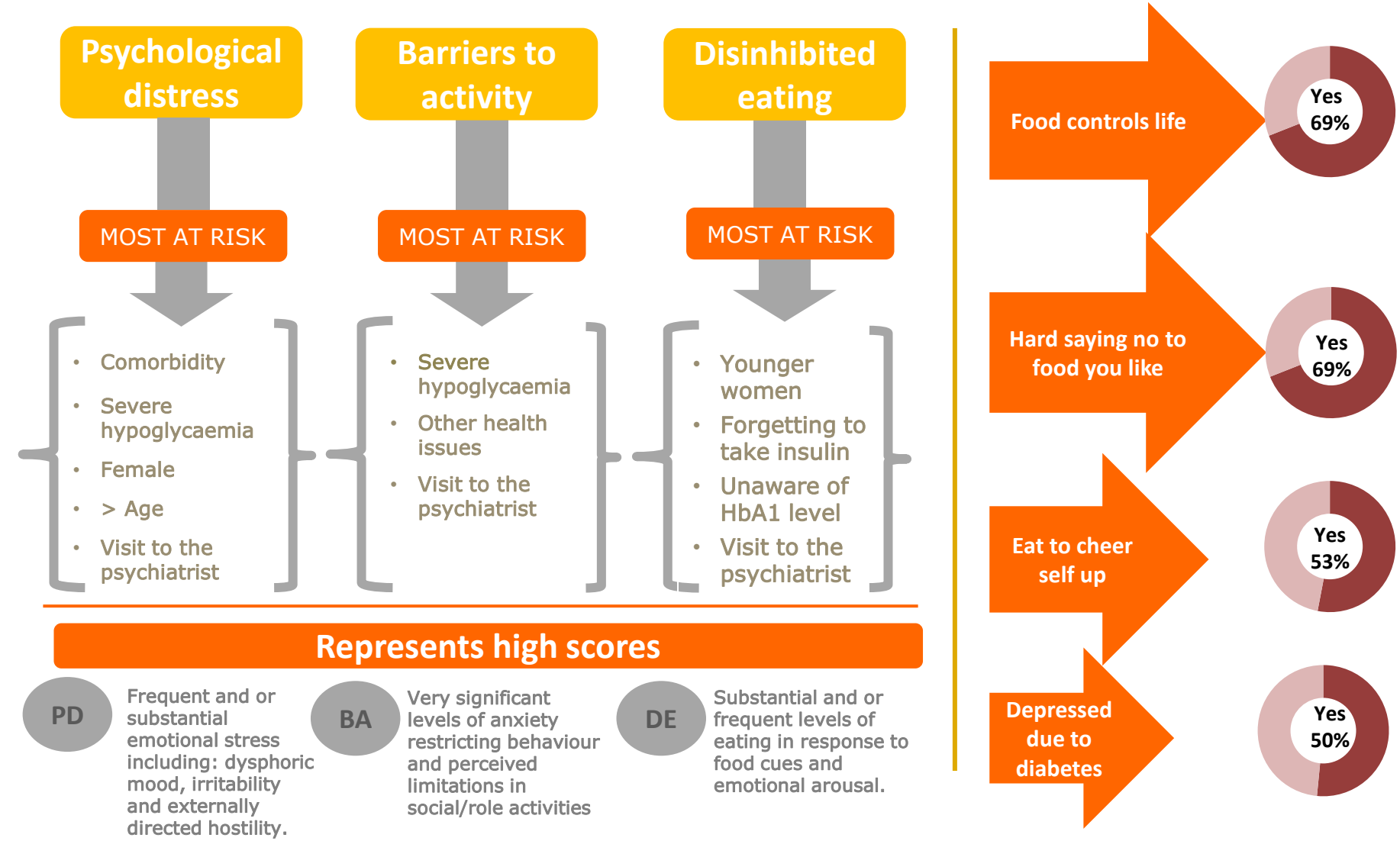
Getting an in-depth look at diabetes with the DHP-18



Factors associated with psychological and behavioural functioning in people with type 2 diabetes living in France.Stephanie Boini, Marie-Line Erpelding et, al.Health Quality of Life Outcomes 2010, 8:124

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Recent Developments

Interpreting the Diabetes Health Profile

The minimally important difference (MID) is the smallest score difference on the Diabetes Health Profile that represents the minimal clinically significant difference.

Investigating the minimally important difference of the Diabetes Health Profile (DHP-18) and the EQ-5D and SF-6Γ in a UK diabetes mellitus population. Mulhern B and Meadows K. Health 5: 1045-1054,2013

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Interpreting the Diabetes Health Profile

A longitudinal dataset from a UK community-based postal survey carried out in one health authority area

- 1092 respondents with a reported diagnosis of Type 1
- Type 2 (n = 999) diabetes…

who fully completed the EQ-5D, SF-6D and DHP-18 at both baseline and 1-year follow-up.

Investigating the minimally important difference of the Diabetes Health Profile (DHP-18) and the EQ-5D and SF-6D in a UK diabetes mellitus population. Mulhern B and Meadows K. Health 5: 1045-1054,2013

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Interpreting the Diabetes Health Profile

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The required MID change in score for the DHP-18 domains

Psychological distress	7 - 11
Barriers to activity	6.5 - 9.9
Disinhibited eating	7.5 - 11.4

Investigating the minimally important difference of the Diabetes Health Profile (DHP-18) and the EQ-5D and SF-6D in a UK diabetes mellitus population. Mulhern B and Meadows K. Health 5: 1045-1054,2013

DHP preference-based measure

- Preference-based scoring using DHP-3D and DHP-5D item scale derived from the DHP-18
- DHP-3D & DHP5D is able to estimate QALYs for the assessment of diabetes specific interventions in existing datasets or in future trials that include the DHP-18 or DHP-1
- The DHP-5D is able to estimate QALYs in data or trials where the DHP-1 and SF-36 are included

Developing preference-based measures for diabetes: DHP-3D and DHP-5D. B. Mulhern, A. Labeit, D. Rowen, E. Knowles, K. Meadows, J. Elliott and J. Brazier. Diabetic Medicine 2017

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Development of an e version of the DHP

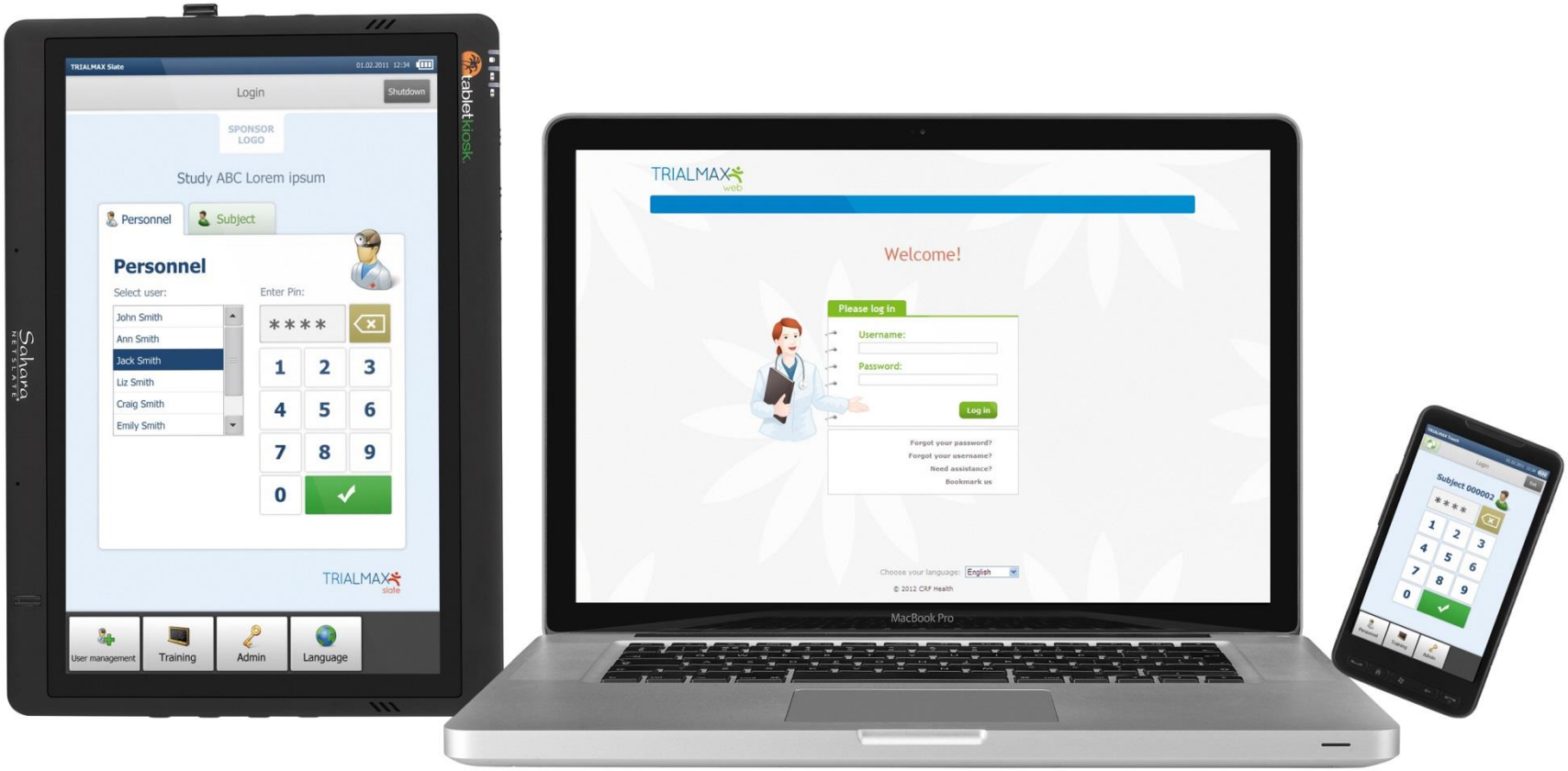

Image source: CRF Health

What is an Author Pre-Approved eCOA?

"An Author pre-approved instrument qualifies the migrated instrument to the author's level of quality and expectation. **Elan Josielewski(Mapi)**

Having followed good practices in instrument migration, it is considered that an Author pre-approved instrument would, with reasonable testing (in line with industry guidelines), demonstrate equivalence".

David Churchman(Oxford University Innovation)

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Advantages of an eDHP

- Facility to apply computerised adaptive scoring
- Collection of symptom events etc. on the same electronic platform
- Real-time DHP-18 scores benchmarked against age, gender, diabetes type, acute complications e.g. hypoglycaemic episodes

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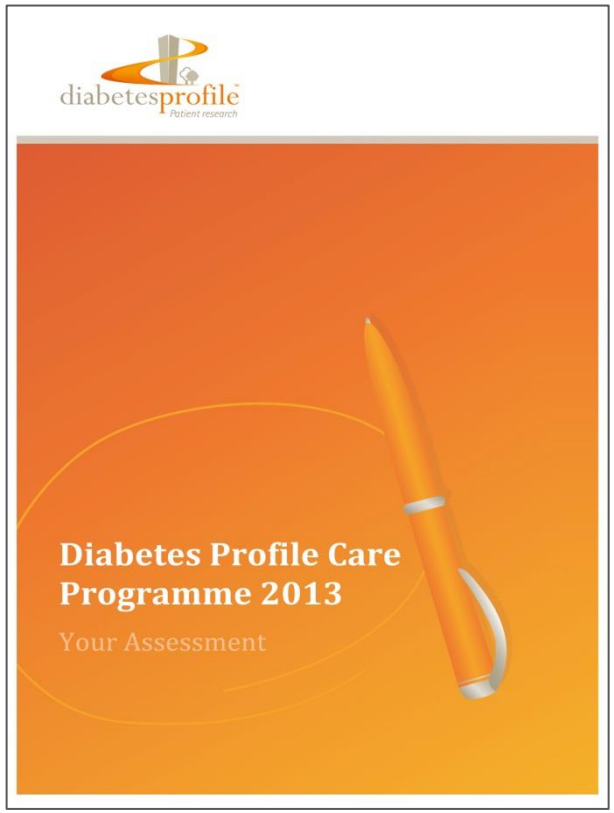
Integration of the DHP-18 into holistic assessment of needs programme for Type 1 and Type 2 patients.



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KEY ATTRIBUTES:
The Diabetes Health Profile

- **Developed** with significant patient input
- **A clearly defined conceptual framework** of the measurement model which conforms to the FDA Final guidance for Industry
- **The measurement of dysfunctional eating behaviour** – which despite its importance in the management of diabetes is absent in other scales
- **Content** No hypothetical questions, relates to real life experiences which respondents identify and engage with
- **Suitable** for use in range of research settings including population surveys, phase III and real world data collection
- **Minimum Important Difference (MID)** Values available
- **Now available** as an eDHP Author approved
- **Now available -** preference-based measures for diabetes: DHP-3D and DHP-5D

For more information from the developer
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www.diabetesprofile.com

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