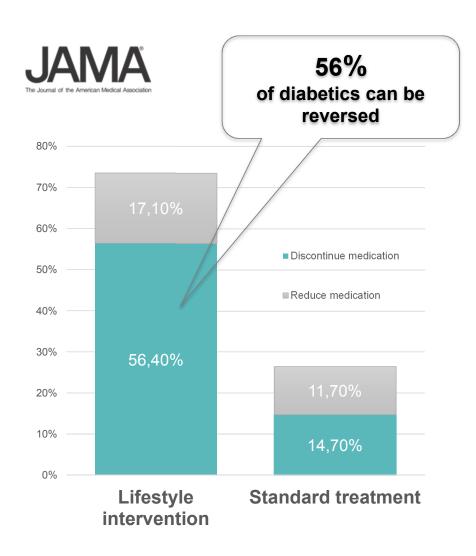


Diabetes can be reversed for 56% via lifestyle change (JAMA study)





- A study published in August 2017 in the respected Journal of The American Medical Association (JAMA) by Professor Bente Klarlund Pedersen (and 14 others) from the University Hospital of Copenhagen documented that type-2 diabetes can be rolled back through lifestyle intervention: 56% can have the diagnosis reverted altogether.
- This intervention is based on six exercise sessions every week, and dietary coaching.



Professor Bente Klarlund Pedersen Copenhagen University Hospital

Authors: Mette Yun Johansen, MSc; Christopher Scott MacDonald, MSc; Katrine Bagge Hansen, MD, PhD; Kristian Karstoft, MD, PhD; Robin Christensen, PhD; Maria Pedersen, MD, PhD; Louise Seier Hansen, MSc; Morten Zacho, MSc; Anne-Sophie Wedell-Neergaard, MD; Signe Tellerup Nielsen, MD, PhD; Ulrik Wining lepsen, MD, PhD; Henning Langberg, DMSc; Allan Arthur Vaag, DMSc; Bente Klarlund Pedersen, DMSc; Mathias Ried-Larsen, PhD

Effect of an Intensive Lifestyle Intervention on Glycemic Control in Patients With Type 2 Diabetes A Randomized Clinical Trial

Meter Van Jahrene, MS/^{1,2}, Christopher Sont MacDonald, MSC^{1,3,3}, Katerine Bugge Harrier, MD, PRO^{(1,1} et al.)

3. Antion Affaires

JMMA, 2017,318(7):637-646. desi/10.1001/jens 2017.0169

Key Points

Question Can an intensive Effetyle intervention achieve glycemic control comparable with standard care in patients with lyay 2 diabetes. Supposed for insess than 10 years, and which was designed to ansess equivalence, the lifestyle intervention vs standard care resulted in a mean change in hemoglability. All, lives of -0.31% vs -0.04% vs. 10 lifestyle intervention vs standard care resulted in a mean change in hemoglability. All principles of supposed equivalence margin of 8.0.4%.

Massing An intensive lifestyle intervention did not meet the criterion for equivalence for glycemic control, but the direction of findings suggests potential benefit.

Abstract

Importance it is unclear whether a lifestyle intervention results is equivalence glycemic control compared with standard care in intensive lifestyle intervention results is equivalent glycemic control compared with standard care, discondarily, leads to a reduction in glucose-lowering medication in participants with type 2 diabetes.

Design, Setting, and Participants andomized, assessor-blinded, single-center study within Region Zeladin and the Capital Region of Demantik Light 2015-14, Supplied Study Light study participants with non-invalin-dependent type 2 diabetes who were diapnosed for less than 10 years see included. Participants were randomly assigned (2.1) stratefied by sex to the lifestyle group (n - 64) or the standard care group (n - 34).

Herrywelines All participants in the lifestyle group (n - 64) or the standard care group (n - 34).

get-driven medical therapy. Additionally, the lifestyle intervention included 5 to 6 weekly aerobic training ses-

Confidential

Introduction to Liva Healthcare – The digital health coaching













Liva Healthcare is a multi-award winning European digital health coaching company. It has head offices in Copenhagen and London and operations in multiple countries across four continents (Europe, Asia, Australia and North America).

- Key competences: Liva helps healthcare players to drive outcomes and adherence through digitallyassisted lifestyle change as an integral part of clinical pathways.
- Track record: Liva was founded by the team behind NetDoctor.com, one of Europe's largest independent health information portals launched in 1998 (visit NetDoktor.de or NetDoctor.co.uk)
- **Platform:** The first version of the digital coaching platform and service launched in 2002. Since then, it has been continuously refined based on best practice and more than 150,000 patients have been through programmes. The disease-agnostic platform is highly flexible and can adapt to programmes in areas including rehabilitation, disease management, prevention, lifestyle change.
- Coaching: Liva also uses its platform to deliver personalised individual coaching and disease management services – all based on proven behaviour change psychology models. Liva is unique in that it uses real coaches, not avatars, for better relationship building throughout a programme.
- Clinical outcomes: Several studies show remarkable outcomes from Liva's services: adherence rates of 60-80% after six months; sustainable weight loss of 4-6% of body weight after 18 months; and a 35-40% reversal rate of pre-diabetic and T2D patients by lowering their Hb1Ac.
- Geographical reach: Liva currently operates in The United Kingdom, Denmark, Sweden, Spain, Singapore, and Canada and is onboarding new clients in Australia, Ireland, Netherlands, Norway, Finland and Germany. As a general rule of thumb, we can be operational in a new country within 3-4 months.
- **Key clients:** Liva has been selected by some of Europe's largest healthcare players including NHS England, AXA PPP Healthcare, and a number of large international pharma and insurance companies.

The Liva tech platform includes five main components







On-boarding site – choose your personal health coach (if free choice of coach is selected in the programme and service design phase)





User apps – Apple and Android native user apps (can be white-labelled as an option)





Coaching and user management platform – up to 2-500 users can be managed per coach (depending on chosen intervention intensity)





Data mining cockpit – real world / real time population statistics



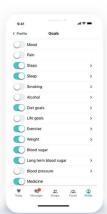


API for Integration to EHR systems – Liva provides an API to integrate into Electronic Health Record (EHR) systems (if relevant and systems are compatible; optional implementation will be according to time and material by rate card).

App'en – Liva set fra borgerens vinkel

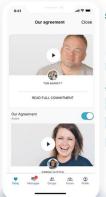


Liva app'ens hovedfunktioner (Native app til både android og IOS)



Skræddersyet livsstilsplan

Borger og vejleder bygger i fælleskab en skræddersyet plan ved at aktivere/deaktivere mål. Planen bygges med fokus på borgers ønsker, behov og formåen.



Aftale

Borger og vejleder udarbejder en aftale. Der nemt kan genses af begge parter om nødvendigt.



Idag siden

- Se vejleder
- Se aftale
- Dage til næste veiledning
- Daglige registreringer



Daglige registreringer

Skridt og motion – Aktivitetsniveau Kost – inkl. Billeder Levemål – Lave 2 ansøgninger, stå op før kl.9 osv.

Medicin – Huske medicin indtag **Rygning** – Registrere det daglige forbrug

Vægt, blodtryk og blodsukker -Vejlederen kan følge proccessen

- Og meget mere



Fremskridt

Borger kan følge sine daglige/ ugentlige/ årlige fremskridt, samt har adgang til personlig statistik på alle livsstilsparametre.



Løbende dialog

Borger og vejleder har løbende asynkron dialog via tekst og video. Derudover kan der sendes pdf'er, links og billeder.



Grupper

Små grupper indeholdende borgere med samme udfordringer eller fra samme område. "rygere", " diabetikere", "bosat nær Odense"



<u>Forum</u>

Interagere med andre borgere – dele erfaringer og få motivation og inspiration.

Vejlederplatform – Liva set fra vejlederens vinkel





Liva fører kalender

Med Liva får du et hurtigt overblik over alle borgere, hvem der skal vejledes i dag og et overblik over processen og hvorledes målsætningerne opfyldes.



Live videomøde

Vejleder kan oprette et live videomøde med en borger både ved opstart eller for at skabe yderligere engagement



Hovedfunktioner til administration af borgere

Veiledning

- Se, følg og ret i målsætninger
- Se resultater og fremskridt
- Video og tekst beskeder
- Journalnoter
- Alt samlet på eet sted



Grupper

Dannelse af grupper fra samme område eller med samme udfordringer. Fx rygestop eller behov for social interaktion, motivation og uddannelse.

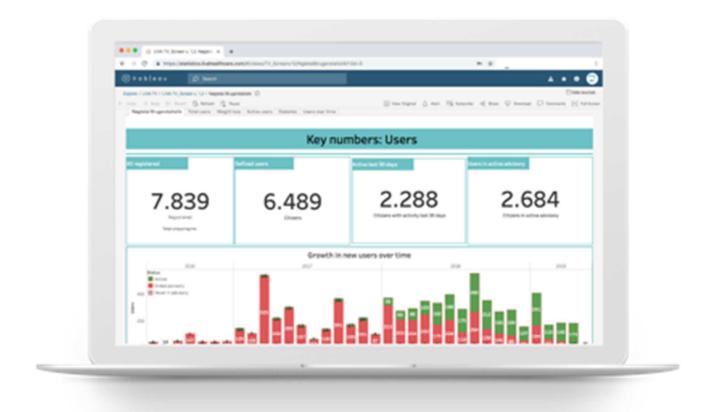
Gruppebeskeder

Send gruppebeskeder til hundredvis af borgere på en gang

Confidential



Overblik – det er nemt at få overblik over de indtastede sundhedsdata



Data security and privacy: Liva is ISO27001 approved and audited by PWC



As a healthcare company that develops and operates healthcare solutions globally, Liva Healthcare takes security and careful data handling extremely seriously. We are committed to complying with all applicable personal data protection laws in our countries of operation, and have taken a number of important steps in that regard, as shown below.

The Liva Healthcare data protection commitment is the basis for our global personal data protection compliance programme, which also includes governance structure, procedures, trainings, and oversight mechanisms to ensure effective data protection and respect for the rights of data subjects.









ISO/IEC 27001:2013 is the international standard Liva is complying to. Our ongoing efforts in remaining best-in-class is continuously audited by REVI-IT (a Danish State Authorised Audit firm specialised in Information security audits and accreditations), delivering independent assessments of our ISMS compliance.

Liva is in full compliance with The General Data **Protection Regulation** (GDPR) (Regulation (EU) 2016/679) which is a regulation intended to strengthen and unify data protection for all individuals within the EU. GDPR took effect 25 May 2018, and replaced the data protection directive (officially Directive 95/46/EC) of 1995.

Our commitment to comply with personal data laws and standards includes compliance with NHS England's Information Governance Toolkit concerning patients and service vendors under the NHS. Among the related laws are The Data Protection Act, and the Confidentiality NHS Code of Practice.

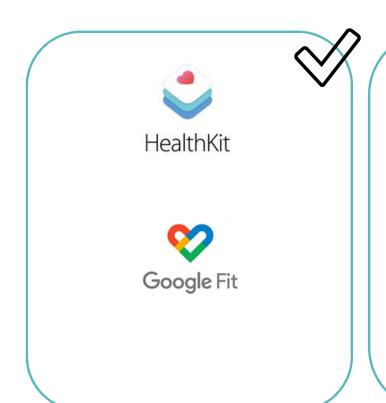
Liva Healthcare operates with the CE marking. which is a certification mark that concludes conformity with health, safety, and environmental protection standards for products sold within the European Economic Area. The CE marking is recognizable worldwide and a token of meeting the requirements of the applicable EC directives.

QIS2015 is the "gold standard" for selfmanagement to assure delivery of consistently high quality.

Device integration for patient data gathering



Liva is fully integrated with both the Apple HealthKit and Google Fit standards, that will cover hundreds of mobile healthcare tracking devices. In addition to the two main standards, Liva is fully integrated with all other major producers of health tracking devices, such as Dexcom, Polar, Fitbit, Withings, iGLucose etc. This means that patients investing in self-monitoring equipment will have all vitals transferred automatically via Bluetooth or Wi-Fi.





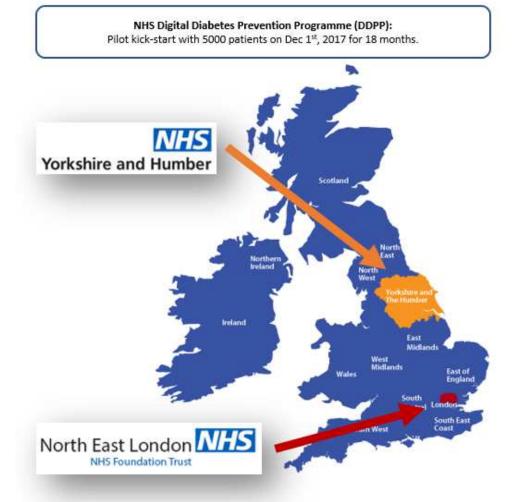
National Health Service UK



Digital Diabetes Prevention Programme

- 5.000 pre-diabetics and obese patients
- Referred via own doctor in general practice
- 1 year of digital life-style intervention (Liva Full-Service)
- Inclusion period: January 2018 December 2019

NHS will enrol 200.000 patients a year (2019-2022) in their NHS DPP program. 20% of these will be digital interventions and Liva just got one of the five seats.



Pre-diabetic outcomes - Active participants

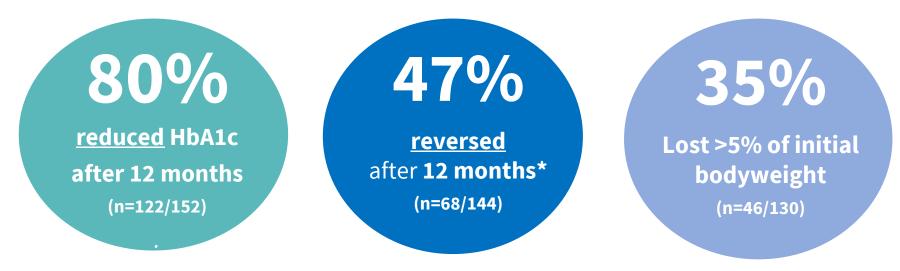


Clinical outcomes, a brief summary - Pre-diabetes real world data

Liva demonstrates marked weight loss and reversal of pre-diabetes in real world setting.

Pre-diabetic outcomes - Active on the serve for at least 11 months, and data in valid range (between 11 to 13 months)

NHS National Diabetes Prevention Programme, UK: 152 prediabetes patients with available 12 months measurements.



^{*} reversed: HbA1c < 42mmol/mol at 12 months when the HbA1c > 42mmol/mol at baseline

Confidential preliminary results from the National Diabetes Prevention Programme UK: 988 prediabetes and overweight patients referred from general practice to 1-year digital lifestyle intervention (Liva full-service). Inclusion from Jan. 2018-December 2018.

Clinical outcomes, a brief summary (pre-diabetes and T2D, real world, real time data)



Liva demonstrates marked weight loss, reversal of pre-diabetes and reversal of diabetes in real world settings:

Pre-diabetic outcomes:

- 65% of prediabetes patients' HbA1c levels are reduced at six months results which are maintained at 12 months
- 40% of prediabetics are reverted to non-diabetic state at six months results which are maintained at 12 months

(Preliminary results – NHS National Diabetes Prevention programme, UK)[ref 1]

- <u>Diabetic patients (type 2)</u>
- 34% are reverted to a non-diabetic state (HbA1c <48mmol/mol) compared to 14% among controls after six months.
- 80% of obese patients lose weight on avg. 5.8 kg ~5.7% of initial bodyweight among intervention group compared to 46% who lose weight in control group on avg. 3.0 kg ~ 3.1% of initial body weight after six months.

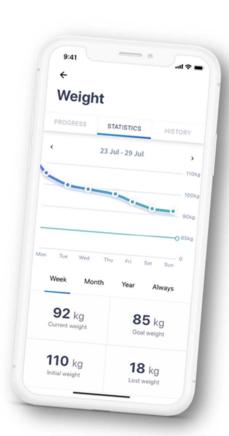
(Preliminary results Liva study in Denmark)[ref 2]



Clinical outcomes, a brief summary (T2D, ongoing RCT study)



- **Design:** Randomized controlled two arm trial implemented in the Region of Southern Denmark.
- Inclusion criteria: Diabetes patients (Hba1c 47+ mmol/mol) and overweight/Obesity (BMI>25). 170 in each arm with 100 in intervention and 70 in the control group. In total 340 patients. Inclusion from Jan 2018-March 2019.
- **Status:** Per October 1st, 2019: 340 patients are onboarded for intervention and control. Within the intervention population 100% have been in intervention for 6+ months
- **Preliminary results:** Please note that these results are preliminary since the study is still ongoing and hence results are strictly confidential.
- Retention:
 - Retention rate at 3 months: 93%
 - Retention rate at 6 months: 85%
 - Retention rate at 9 months: 76%
- Outcomes among overweight/obese patients at six months: 80% lose weight on avg. 5.8 kg ~ 5.7% of initial bodyweight among intervention group compared to 46% who lose weight in control group on avg. 3.0 kg ~ 3.1% of initial body weight.
- Outcomes among diabetes patients at six months: 34% are reverted to a prediabetic state (HbA1c <48mmol/mol) compared to 14% among controls. 82% lose weight on avg. 5.2 kg ~ 5.1% of initial bodyweight among intervention group compared to 69% who lose weight in control group on avg. 2.8 kg ~ 2.6% of initial body weight.



Clinical outcomes, a brief summary (overweight and obese patients)



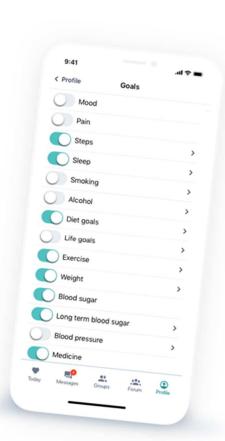
- Avg. 6.3% bodyweight reduction (or 6.8 kg weight loss) among diabetes patients after nine months intervention in a municipal real-life setting (Komkova 2019)
- Liva is cost effective already after one year of implementation seen in a municipality perspective (ApEHR 2017) [Ref 3]
- 7 kg weight loss sustained at 20 months in Denmark (Brandt 2011)

Sources:

[Ref 1] Confidential preliminary results from the National Diabetes Prevention Programme UK: 988 prediabetes and overweight patients referred from general practice to 1-year digital lifestyle intervention (Liva full-service). Inclusion from Jan. 2018-December 2018.

[Ref 2] Confidential preliminary results from Liva Study DK: Randomized controlled trial with 200 overweight and diabetes patients in a 1-year intervention, (Liva full-service). Inclusion from Jan 2018-Jan 2019.

[Ref 3] Cost-effective analysis of implementation of Liva intervention from the perspective of a Danish municipality as the payor of the service. Conducted by the independent research organization Applied Economics and Health Research, (ApEHR). See full report at https://livahealthcare.com/wp-content/uploads/2018/11/Report_Apehr_2017.pdf



Internal Published Studies on Liva Platform and Intervention (1/4)





7.0 kg weight loss attained in 4 months and sustained after 20 months







Weight loss at 20 months

- Average 7.0 kg weight loss attained after 4 months
- This weight loss is further sustained throughout follow-up to 20 months

Intervention

- Combination of face-to-face coaching with online coaching in a GP setting
- Increased exercise and low calorie diet advice

Conclusion

 Findings may indicate the efficacy of intervention as a way to efficiently and costeffectively drive sustainable weight loss for a large population

Published data

5.4 kg weight loss sustained after 12 months







Weight loss at 12 months

- Average 5.4 kg weight loss compared to 2.8 kg in a control group receiving usual care
- 61% of patients remained engaged in the program for the full 12 months

Intervention

- Combination of in person coaching with online coaching
- Increased exercise and low calorie diet advice within National Health Service (NHS) England



- Brandt et al., "Sustained Weight Loss during 20 Months using a Personalized Interactive Internet Based Dietician Advice Program in a General Practice Setting", International Journal on Advances in Life Sciences, 2011; 3
- Haste et al., "Web-Based Weight Loss Intervention for Men with Type 2 Diabetes: Pilot Randomized Controlled Trial." JMIR, 2017; 2

Internal Published Studies on Liva Platform and Intervention (2/4)

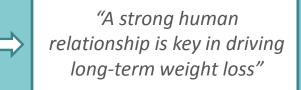




A strong human relationship is the most important driver of long-term weight loss









Conclusions

Conclusions

- This study found that the most important driver in long-term weight loss was a strong relationship between the patient and a healthcare professional
- Continuous positive support was perceived as an important factor for long-term success
- Collaborative e-health tools are able to support the relationship between patients and health professionals, and drive behavioral changes

General practitioners are willing to use eHealth more frequently for patients







"General practitioners are willing to use eHealth more frequently for patients – however education is needed"



GPs are familiar with behavioral change techniques and ready to use them in e-health for patients whey can assist in optimising processes and do not hinder other forms of treatment

 Looking ahead, education of GPs and recognizing patients' ability and preference to use e-health are needed



Brandt et al., "Drivers for successful long-term lifestyle change, the role of e-health: A Qualitative Study", BMJ Open, 2018; 8

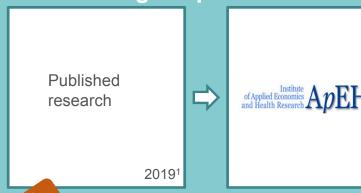
Brandt et al., "General practitioners' perspective on eHealth and lifestyle change: Qualitative Interview Study", JMIR mHealth and uHealth, Vol 6, no 4, 2018

Internal Published Studies on Liva Platform and Intervention (3/4)



oublished date

Predicting Dropouts from life style interventions: Analysis of Methods and Predictors





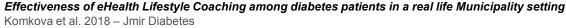
Conclusions

- Average 3.5% body weight reduction (3.9 kg) among Type 2 diabetes patients on Liva platform for 6 months (pilot data)
- Prior research indicates that a 1% reduction in body weight among diabetes patients corresponds to 3.1% reduction in societal costs
- Potential for societal cost savings of €2,140 per patient per year
- Liva's intervention provides a cost-effective solution for municipalities, saving money and improving outcomes within a year of initiation

aublisher date

Is Lifestyle Coaching for diabetes patients cost effective in a municipal setting?





Objective

- Assess effectiveness of e-health lifestyle coaching among diabetes patients in a municipal setting
 Methods
- An observational study examining the effect of eHealth lifestyle coaching on self-reported weight change among 103 obese diabetes patients, in programme for between 3 and 12 months, in a municipal setting.

Results

- Significant weight reduction, on average 4.3% of the initial body mass, corresponding to 4.8 kg over mean period of 7.3 months.
- Annual saving of 2667€ per patient
- Patients who had used the eHealth tool for over 9 months achieved a weight reduction of 6.3% or 6.8 kg.

- Sonenshine Fulford Group 2. JMIR Di
- 1. Economic report performed by Applied Economics and Health Research, August 2017
 - JMIR Diabetes. 2019 Mar 12;4(1):e12140. doi: 10.2196/12140. Electronic Health Lifestyle Coaching Among Diabetes Patients in a Real-Life Municipality Setting: Observational Study

Internal Published Studies on Liva Platform and Intervention (4/4)



Published data

Predicting Droputs from Life style interventions: Analysis of methods and predictors

Department for Health Informatics and Technology





"Data mining methods can support health coaches in preventing drop-out from digital interventions" This study aimed to gain insight into the causes of attrition for patients in an electronic health intervention and evaluate if attrition can be predicted and consequently prevented

Methods

Data from 2684 patients using an eHealth platform were iteratively analyzed using logistic regression, decision trees, and random forest models.

Conclusions

Dropouts from eHealth lifestyle interventions can be predicted supporting health coaches in preventing attrition by receiving proactive warnings. The best performing predictive model was found to be the random forest

Scientific Research Studies on Liva Underway (1/4)



What is the effect of eHealth intervention among chronic heart disease patients?







A highly specialised hospital in Denmark





Aarhus University Hospital



Effectiveness of a complex interactive eHealth intervention (Liva) on patient-reported and clinical outcomes in patients with an implantable cardioverter defibrillator [ACQUIRE-ICD Trial]: Study Protocol of a National Danish Randomized Controlled Trial

Pedersen et al. 2018. In writing for publication. Study in progress

Objective

 To evaluate the effectiveness of the ACQUIRE-ICD care innovation, a comprehensive and interactive ehealth intervention, on patient-reported and clinical outcomes

Methods

 A multi-centre, prospective, two-arm, unblinded randomized controlled superiority trial enrolling 478 patients implanted with a first-time ICD or CRT-D from six implanting centres in Denmark

What is the effect of individualised treatment delivered digitally among diabetes patients?





Aarhus University Hospital





Protocol for the specialist supervised individualised multifactorial treatment of new clinically diagnosed Type 2 diabetes in General practice (IDA): A Prospective controlled multi-centre open-label intervention study1

Stidsen et al. (2017). Study in Progress

Objective

· A multifactorial intervention study designed to test whether individualised treatment, based on pathophysiological phenotyping and individualised treatment goals, improves Type 2 diabetes (T2D) outcomes

Methods

 A prospective controlled multicentre open-label intervention study, drawing on the longitudinal cohort of the Danish Centre for Strategic Research in Type 2 Diabetes (DD2) and individualized lifestyle advice using a complex e-health solution (Liva)



Stidsen et al. Protocol for the specialist supervised individualised multifactorial treatment of new clinically diagnosed Type 2 diabetes in general practice (IDA): A Prospective controlled multicentre Confidential open-label intervention study. Diabetes and Endocrinology, BMJOpen - 2017-017493

Scientific Research Studies on Liva Underway (2/4)



UP coming

What is the effect of Liva among overweight and diabetes patients?







Clinical and economic effect of a primary care anchored collaborative eHealth lifestyle coaching intervention among diabetes patients and overweight patients – A 2-year Randomised Controlled trial (Liva Study) Study in Progress (Inclusion period 1st of Jan. 2018-1st of Feb. 2019)

Objective

• To assess the effect of Liva intervention among overweight citizens at risk of developing chronic disease and current diabetes patients motivated to change lifestyle to improve their disease regulation

Methods

• A two arm multi-centre randomised controlled trial with 1-year intervention and 1-year retention including 340 overweight and diabetic patients (170 in each arm).

Results

• 301 enrolled. First 6 months results among 91 participants show that in the intervention group, 83% are still active and among overweight patients, a weight loss of avg. 4.8 kg is seen compared to a weight increase of 0.5 kg among controls.

UPcomin.

What is the effect of Liva intervention when anchored in General Practice?



eHealth Lifestyle Coaching among newly diagnosed diabetes patients with integration to GP systems in a primary care setting – DICTA study

Feasibility study started up August 2019 with 75 patients in 5 GPs

Objective

 To analyse the effects of a complex intervention using trained dieticians in a general practice setting combined with the Liva platform and integration to GP systems compared with conventional treatment.

Methods

 A randomised 2-year intervention trial in a Danish general practice setting including 300 newly diagnosed diabetes patients.

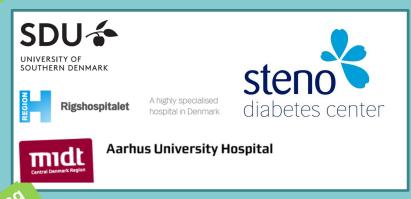


Scientific Research Studies on Liva Underway (3/4)



UPcoming

What is the effect of digital health promoting initiative in families where the mother had gestational diabetes?





- Face-it is a complex, multi-level health promotion intervention aimed at families, where the mother had gestational diabetes mellitus (GDM) running from 2018-2022.
- RCT with 1-year follow-up.
- Inclusion period from 1st of February 2019.
- The intervention is delivered via two sources; (i) by health visitors with focus on the general wellbeing of the family, (ii) an interactive digital component (LIVA).

Objectives

- Reduce the risk of type 2 diabetes (T2DM) and increase quality of life among women with earlier gestational diabetes and their families
- Strengthen the collaboration and coordination across healthcare sectors and disciplines to improve coherence in the care pathway for women with earlier gestational diabetes and their families

JPCOMI.

What is the effect of a digital delivered mediteranian diet intervention in women with previous gestational diabetes?







The intervention

- The Merit study: A Mediterranean diet intervention delivered through an interactive digital component (LIVA).
- Pilot study running from January 2019 and 1 year including 60 women with previous gestational diabetes.

Objectives

- Investigate the effect of introducing a Mediterranean diet for women with previous gestational diabetes
- Reduce the risk of type 2 diabetes (T2DM) and increase quality of life among women with earlier gestational diabetes and their families

Scientific Research Studies on Liva Underway (4/4)



Horizon 2020 - IMPACT DIABETES BUMP 2 BABY

Her må vi se om vi kan finde alle parternes ikoner. Er der evt en frisk stud med der kan det?



The intervention

- A low-resource system level intervention for healthy gestational weight gain and improved postnatal
- A multi-sited 1-year RCT identifying pregnant women at highest risk of developing T2DM running from 2020-2022. 1 year follow up.
- · supports self-management of modifiable lifestyle risk factors through personalised health coaching service
- Inclusion period from 1st of January 2021.
- It will guide a woman's journey from pregnancy to birth and beyond covering the infant's first '1000 days'

Objectives

- 800 women, (400 in intervention), will be undertaken across four countries: Ireland, England, Australia and
- Focus on scaling up in a cost-effective manner that can be used by a wide audience.

Ditto her

Lev Godt

The intervention

- A cross-sectoral project that helps people with Diabetes Type 2 maintain good living habits
- The privat GP, the municipality and local gymnastics- and health associations are coordinating the help
- · Focus on long-term help-settings, social relations, cost-effectiveness and digital educational skills among heathcare professionals.

- 6 municipalities in Region Zealand, Steno Diabetes Centre Zealand. Local Diabetes Associations, DGI, Absalon
- · Reduce the risk of type 2 diabetes and increase quality of life among people with type 2 diabetes and their families in a cost-effective manner.



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