Studies on patients with DM1

Study name registration number Design	**Setting** Place, setting and time	**Population** Inclusion / Exclusion criteria	Characteristics	**Intervention vs. Control** Description with duration	**Outcomes** Primary and secondary	**Results** Longest follow-up period with intervention effects (IG vs. CG) with SD, 95%-CI or p value
Educational strategies						
Malipa 2013 RCT	Zambia	DM1, 16-19 yrs	n=40 55% females 16-17 yrs: 35 % 18-19 yrs: 65 % Compliance: worse in IG 26.4 vs. 14.6 (p=0.001) Impact of diabetes: 20.5 Worries about diabetes: 20.5 Satisfaction with life: 20.5	IG (n=20): 1 meeting /wk over 8 wks CG (n=20); waiting list Duration: 8 wks	Compliance to treatment (Rating scale for compliance) Quality of life (impact and worries about diabetes, satisfaction with life)	After 2 months: Compliance: better in IG (11.0 vs. 30; p<0.001) Impact of diabetes: better in IG (16.8 vs. 24.2; p=0.045) Worries about diabetes: better in IG (14.32 vs. 26.68; p=0.001) Satisfaction with life: better in IG (28.5 vs. 12.5; p<0.001)
Strategies to enhance physical activity						
Salem 2010 RCT 02/2009-11/2009	Egypt, urban	DM1 for ≥3 years, 12-18 yrs, HbA1c ≥7.5 % for ≥6 months no significant diabetic complications limiting exercise like, uncontrolled hypertension, diabetic keto-acidosis, severe hypoglycemia within the past 3 months, patients on lipid lowering therapy	n=196 61.7 % female age (yrs): 14.78 ± 2.31 HbA1c (%): 8.7±1.7 duration of diabetes (yrs): 4.6 ± 1.9	IG2 (n=73): attended exercise sessions three times/week vs. IG 1 (n=75): attended exercise sessions once times/week vs. CG (n=48): no exercise Duration: 6 months	glycemic control, plasma lipids values, blood pressure, severity and frequency of hypoglycemia, anthropometric measurements and insulin dose	Change over 6 months: HbA1c (%): Benefit for IG2 and IG1: 7.8 ± 1.0 vs. 8.1 ± 1.1 vs. 8.9 ± 1.3% (p=0.2)
Strategies on nutrition						
Abdulrhman 2013 NCT01554566 Cross-over	Egypt, urban, tertiary care 01/2010 -	DM1, age > 2 yrs, HbA1c< 10 % no renal or hepatic impairment, coexisting	n=20 50 % females age (yrs): 11.3 ± 4.3 duration of diabetes (yrs): 4.7±4.5	IG/ CG (n=10): Honey consumption (0.5 ml/kg body weight per day) vs.	Primary: serum lipids, c-peptide Secondary: anthropometric measures (e.g. BMI), fasting and 2h-	After 12 weeks: (IG/CG vs. CG/IG): HbA1c (%): • Benefit with CG/IG: 6.7±0.9 vs. 5.9±0.8 (p<0.01) • no differences in change in period 1: -

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RCT	10 / 2011	diseases or therapies that may affect body weight or serum lipids	HbA1c (%):7.21± 0.76 fasting glucose (mg/dl): 154.5±22.5	CG/IG (n=10): changed after 12 wks and received than honey Duration: 12 wks.	postprandial glucose, HBA1c, serum lipid profile	5.83 ± 13.66 vs. 2.94±8.82 (p=0.105) Fasting glucose (mg/dl): • benefit with CG/IG: 142.7 ±26.6 vs. 116.7±19.4 (p<0.01) benefit with IG/CG in period 1:-21.51 ± 10.84 vs. -0.08±5.14 (p=0.001)
Mohamad 2009 RCT	Egypt, urban	DM1, age 17 to 20 yrs no acute metabolic complications like diabetic ketoacidosis, hypoglycaemia, cardiovascular events, renal or acute infections	n=64 30 % female age (yrs): 19.9±6.8 HbA1c (%): 9.52±2.08 fasting glucose (mg/dl): 228.7±13.5 BMI (kg/m²): 18.82±3.01	IG (n=27): camel milk (500 ml) +usual care vs. CG (n=27): usual care for diabetes (i.e. diet, exercise, insulin mixtard) Duration: 16 weeks	Not specified: HbA1c, human C-peptide, lipid profile, serum insulin, anti-insulin antibodies, creatinine clearance, albumin extraction in 24 h urine, BMI, Diabetes QoL score, fasting glucose	After 16 wks HbA1c (%): Benefit for IG: 7.16±1.84 vs. 9.59±2.05 fasting glucose (mg/dl): benefit for IG: 227.2±17.7 vs. 98.9±16.2
van der Hoogt 2017 cross-over RCT	South Africa	DM1, age 4-17 yrs on insulin pump therapy, HbA1c>9,6% for ≥3months, BMI/age z.score -1 to < 3, total daily insulin use of >0,5 u/kg no remission of diabetes, smoking, coeliac disease, cystic fibrosis, diseases or medication that are associated with delayed gastric emptying or altered digestation, glucocorticoids, oral diabetic drugs, no acute illnesses	n=32 41% female age (yrs): 10.4±4.0 HbA1c (%): 8.2±0.8 duration of Diabetes (yrs): 3.5 (1.5-8.0)	IG1 (n=22): 1 home-based low fat and protein meal vs. IG2 (n=22): 1 high fat and protein meal with identical carbohydrate content two meals were consumed at dinner time (18:00) under parental supervision at least 1 day apart within one month Duration: 3months	primary: peak sensor glucose value post-meal, time to peak sensor glucose, time of first and largest correction bolus, total correction insulin, total meal insulin, additional insulin required ,area under the sensor glucose response curve (AUC) (≥ 8 mmol/L), duration of elevated post-prandial glucose	Change over 12 weeks Occurance of hypoglycaemic events: 7 (32 %) vs. 1 patients after IG1 vs. IG2
Medical device						
Elbarbary 2016 RCT	Egypt, urban 06/2014-07/2014	DM1, adolescents and adults who wished to fast the month of Ramadan with insulin pump for ≥6 months and attending the whole	n=73 68.3% female age (yrs): 15.6±2.7 HbA1c (%): 7.65±0.9 BMI (kg/m²):	Insulin pump therapy during Ramadan fasting IG (n=25): sensor with low glucose	Primary: hypoglycaemia Other: glucose value, number of 'full fasted days', emergency hospital visit for diabetes-related	After 1 months: Glucose value (mg/dl): 152.5±17.3 vs. 141±33.8 (p=0.9) Complications: Number of hypoglycaemic excursions:

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		education session 2 months before fasting and committed to follow-up the given instructions no diabetic ketoacidosis, episodes of severe hypoglycaemia or symptoms of uncontrolled diabetes in the last 6 months, diabetic microvascular complications or macrovascular disease, pregnant women	24.56±3.5 duration of diabetes (yrs): 5.8±2.9 on pump therapy (yrs): 1.73±0.99	suspension activation vs. CG (n=35): sensor without low glucose suspension activation Duration:1 month	problem	3.68±1.62 vs. 6.7±2.1 (p=0.001) Number of hyperglycaemic excursions: 17.0±4.0 vs. 23.0±7.6 (p=0.001) No severe hypoglycaemic events, no episodes of diabetic ketoacidosis, no hyperglycaemic events associated with ketosis no deaths or device-related SAE
Pharmacological Strategies						
Elbarbary 2018 NCT0292825 RCT	Egypt, urban	DM1, age: 9 - 18 yrs, ≥ 5 yrs disease duration, active diabetic nephropathy in the form of microalbuminuria, HbA1c ≤ 8.5 % no infection, renal impairment due to other causes other than diabetes, other diabetic complications, hypersensitivity to carnosine	n=90 52.3 % female age (yrs): 12.85±3.1 HbA1c (%):7.85±1.95	IG (n=45): 1 g/d carnosine vs. CG (n=45): control/placebo group Patients in both groups received oral ACE-Is captopril 25 mg Duration: 12 wks	Primary: change in tubular damage marker Secondary: urinary albumin excretion (UAE), oxidative stress markers Safety: any AE	After 12 wks: HbA1c (%): • Benefit for IG: 7.4 ±1.3 vs. 8.3±2.4 • change -9.88±7.12 vs. 3.89±2.28 (p=0.005) No adverse reactions were reported
Elbarbary 2020 NCT03594240 RCT	Egypt, urban 03/2017-03/2018	DM1 on insulin therapy with > 5 yrs of disease duration, 12-18 yrs, active nephropathy, HbA1c< 8.5 %, no infections, renal impairment due to other causes than diabetes, other diabetic complications ,	n=80 55% female age (yrs): 15.4 ± 1.6 HbA1c (%):7.95±0.5 fasting glucose (mg/dl): 114.5±21.8 duration of diabetes (years): 8.65 ± 2.65	both groups received oral angiotensis-converting-enzyme inhibitors (captopril) IG (n=40) oral vitamin B complex (B1,B6,B12) once daily vs.	Primary: Cystatin C diet, physical activity, and metformin dosage	after 12 weeks HbA1c (%): Benefit for IG: 7.5±0.6 vs. 8.0±0.6 Fasting glucose (mg/dl): 107.7±14.1 vs. 116.4±17 (p=131)

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		elevated liver enzymes, hyper-or hypothyroidism, hypertension, neoplasm, taking any vitamins or food supplements within 1 months before study start		CG (n=40): placebo Duration: 12 weeks		

BMI: Body mass index; CG: Control group; CG/IG: Crossover from CG to IG; CI: Confidence interval; DM1: Type 1 diabetes; FPG: fasting plasma glucose; HbA1c: haemoglobin A1c; IG/CG: cross over from IG to CG; IG: intervention group; n: number of participants ;RCT: randomized controlled trial; SD: Standard-deviation; wks: weeks; yrs: years

Supplementary Table 2: Characteristics and results of studies on patients with DM1