Initial sertraline treatment (N = 115) 12-weeks

Primary outcome 
>= 50% reduction HAMD-baseline score or HAMD <= 7

Secondary outcome 
all other variables

Initial responders included
In the long-term phase of RCT, N = 182*

Sertraline responders
sustained treatment & diabetological treatment as usual, N = 91*

CBT responders
no further CBT treatment, diabetological treatment as usual, N = 91*

Sertraline non-responders and CBT non-responders
Exclusion of RCT. Treatment recommendation to physician

Note: *estimated

Diabetes education

Randomization

CBT (N = 115) 10 x 2 h within 12-weeks

Post-treatment assessment

Note: *estimated

Primary Outcome
-HbA1c

Secondary outcome
- Remission of Depression (SCID)
- Depression improvement (HAMD)
- Generic and diabetes-specific quality of life (SF-36, PAID)

Baseline assessment

Diabetes education

Randomization

Short-term phase of the RCT
12-week open-label trial CBT vs. sertraline

12-month follow-up

Long-term phase of the RCT
one-year follow-up for sertraline responders vs. CBT responders

High-risk patients
Insulin-treated type 1 or type 2 diabetes mellitus with major depression and HbA1c > 7.5%