**Supplemental Table S1. HbA1c-based adjustment of diabetes therapy**

**a) For HbA1c <7.0% (53 mmol/mol),** resume the pre-admission treatment regimen.

**b) For HbA1c 7.0 to 7.9% (53-63 mmol/mol)**

* Patients who did not take insulin before admission, discharge on optimized pre-admission treatment regimen (see definition below) or add a non-insulin agent if the prior regimen was already optimal.
* Patients who took basal insulin but not prandial insulin before admission, increase the home daily dose of basal insulin by 10-15% in addition to any non-insulin pre-admission treatments.
* Patients who took multiple daily insulin injections (MDI) before admission, increase the home total daily dose of insulin by 10-15% in addition to any non-insulin pre-admission treatments.

**c) For HbA1c 8.0 to 9.0% (64-75 mmol/mol)**

* Patients who did not take insulin before admission, discharge on 50% of the last inpatient insulin glargine daily dose or 0.2 units/kg in addition to the pre-admission treatment regimen, which should be optimized.
* Patients who took basal insulin but not prandial insulin before admission, discharge on 50-80% of the last inpatient insulin glargine daily dose or increase the home daily dose of basal insulin by 10-15% and/or add rapid-acting insulin before the largest meal at 50-80% of the last inpatient dose or 0.1 units/kg in addition to any non-insulin pre-admission treatments.
* Patients who took multiple daily insulin injections (MDI) before admission, discharge on 50-80% of the last inpatient total daily insulin dose or increase the home total daily dose of insulin by 10-15% in addition to any non-insulin pre-admission treatments.

**d) For HbA1c >9.0% (75 mmol/mol)**

* Patients who did not take insulin before admission, discharge on 80-100% of the last inpatient insulin glargine daily dose or 0.3 units/kg in addition to the pre-admission treatment regimen, which should be optimized.
* Patients who took basal insulin but not prandial insulin before admission, discharge on 80-100% of the last inpatient insulin glargine daily dose or increase the home daily dose of basal insulin by 20-30% and/or add rapid-acting insulin before the largest meal at 80-100% of the last inpatient dose or 0.1 units/kg in addition to any non-insulin pre-admission treatments.
* Patients who took multiple daily insulin injections (MDI) before admission, discharge on 80-100% of the last inpatient total daily insulin dose or increase the home total daily dose of insulin by 20-30% in addition to any non-insulin pre-admission treatments.

For all subjects with baseline HbA1c >7.0% (53 mmol/mol), non-insulin diabetes therapy was optimized, defined as using the next higher dose up to the maximum tolerated dose. Only FDA-approved diabetes therapies were used in the study.

**Supplemental Table S2. Outpatient basal insulin dose adjustment**

|  |  |
| --- | --- |
| **Fasting blood glucose** | **Basal insulin dose adjustment** |
| If mean **FBG > 180 mg/dL** for the last 2 consecutive days and no episodes of hypoglycemia | Increase daily basal dose by 4 U |
| If mean **FBG > 140 mg/dL** for the last 2 consecutive days and no episodes of hypoglycemia  | Increase daily basal dose by 2 U |
| If mean **FBG between 100 to 140 mg/dL** for the last 2 consecutive days and no episodes of hypoglycemia | No Change |
| If any FBG between 70 – 99 mg/dl | Decrease by 4 U or 10% of total daily basal dose |
| If any FBG < 70 mg/dl | Decrease by 8 U or 20% of total daily basal dose |
| If any FBG < 40 mg/dl | Decrease total daily basal dose by 30% |

FBG=Fasting blood glucose; Hypoglycemia=typical symptoms (e.g., sweating, tremor, acute hunger, anxiety) and/or blood glucose <70 mg/dL

**Supplemental Table S3. Outpatient prandial/pre-meal insulin dose adjustment based on subsequent mealtime/HS BG values**

|  |  |  |
| --- | --- | --- |
| **Pre-meal Dose, U**  | **BG 70 – 100 mg/dl\***  | **BG 141-180 mg/dl\*\***  |
| ≤ 10 U  | Decrease by 1 U  | Increase by 1 U  |
| >11- 19 U  | Decrease by 2 U  | Increase by 2 U  |
| ≥ 20 U  | Decrease by 3 U  | Increase by 3 U  |
| **Pre-meal Dose, U**  | **BG 40-70 mg/dl x 1** | **BG 180-240 mg/dl x 1** |
| ≤ 10 U  | Decrease by 2 U  | Increase by 2 U  |
| >11- 19 U  | Decrease by 3 U  | Increase by 3 U  |
| ≥ 20 U  | Decrease by 4 U  | Increase by 4 U  |
| **Pre-meal Dose, U**  | **BG < 40 mg/dl x 1\*\*\***  | **BG > 240 mg/dl x 1** |
| ≤ 10 U  | Decrease by 4 U  | Increase by 3 U  |
| >11- 19 U  | Decrease by 6 U  | Increase by 4 U  |
| ≥ 20 U  | Decrease by 8 U  | Increase by 5 U  |

**Pre-meal insulin dose adjustment is based on the subsequent BG value, e.g., pre-breakfast insulin dose is based on the pre-lunch BG.**

**\*** If > ½ of the mealtime/HS BG values for the week were below target.

\*\*If > ½ of the mealtime/HS BG values for the week were above target.

\*\*\* Decrease by 30-40% in the event of severe hypoglycemia (mealtime/HS BG < 40 mg/dl).

BG=blood glucose; Mealtime/HS=pre-lunch, pre-dinner, or bedtime

The above algorithm provides recommended insulin doses and may have been modified based on clinical judgment of the investigator or co-investigator.

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial

|  |  |  |  |
| --- | --- | --- | --- |
| Section/Topic | Item No | Checklist item | Reported on page No |
| Title and abstract |
|  | 1a | Identification as a pilot or feasibility randomised trial in the title | 1 |
| 1b | Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials) | 1 |
| Introduction |
| Background and objectives | 2a | Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial | 2 |
| 2b | Specific objectives or research questions for pilot trial | 2 |
| Methods |
| Trial design | 3a | Description of pilot trial design (such as parallel, factorial) including allocation ratio | 2 |
| 3b | Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons | n/a  |
| Participants | 4a | Eligibility criteria for participants | 2 |
| 4b | Settings and locations where the data were collected | 2 |
|  | 4c | How participants were identified and consented | 2 |
| Interventions | 5 | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered | 2-4  |
| Outcomes | 6a | Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed | 4 |
| 6b | Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons | None |
|  | 6c | If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial | n/a |
| Sample size | 7a | Rationale for numbers in the pilot trial | 4 |
| 7b | When applicable, explanation of any interim analyses and stopping guidelines | n/a |
| Randomisation: |  |  |  |
| Sequence generation | 8a | Method used to generate the random allocation sequence | 2 |
| 8b | Type of randomisation(s); details of any restriction (such as blocking and block size) | 2  |
| Allocationconcealmentmechanism | 9 | Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned | 2 |
| Implementation | 10 | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions  | 2 |
| Blinding | 11a | If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how | n/a |
| 11b | If relevant, description of the similarity of interventions | n/a |
| Statistical methods | 12 | Methods used to address each pilot trial objective whether qualitative or quantitative | 4-5 |
| Results  |
| Participant flow (a diagram is strongly recommended) | 13a | For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective | 5 |
| 13b | For each group, losses and exclusions after randomisation, together with reasons | 5 |
| Recruitment | 14a | Dates defining the periods of recruitment and follow-up | 5 |
| 14b | Why the pilot trial ended or was stopped | 4 |
| Baseline data | 15 | A table showing baseline demographic and clinical characteristics for each group | 6-8 |
| Numbers analysed | 16 | For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group | 9 |
| Outcomes and estimation | 17 | For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group | 9 |
| Ancillary analyses | 18 | Results of any other analyses performed that could be used to inform the future definitive trial | 9-10 |
| Harms | 19 | All important harms or unintended effects in each group (for specific guidance see CONSORT for harms) | 9 |
|  | 19a | If relevant, other important unintended consequences | n/a |
| Discussion |
| Limitations | 20 | Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility | 10-11 |
| Generalisability | 21 | Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies | 12  |
| Interpretation | 22 | Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence | 10-11 |
|  | 22a | Implications for progression from pilot to future definitive trial, including any proposed amendments | 11 |
| Other information |  |
| Registration | 23 | Registration number for pilot trial and name of trial registry | 2 |
| Protocol | 24 | Where the pilot trial protocol can be accessed, if available | 2 |
| Funding | 25 | Sources of funding and other support (such as supply of drugs), role of funders | 11 |
|  | 26 | Ethical approval or approval by research review committee, confirmed with reference number | 2 and 11 |

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.