**Figure 1. Flow of the Study Design**

- **Enrollment**: Assessed for eligibility (n=...) (Telephone Screenings)
  - Excluded
    - Not meeting inclusion criteria (n=...)
    - Declined to participate (n=...)

- **Completed Screening/Baseline Visit (n=...)**
  - Excluded
    - Not meeting inclusion criteria (n=...)
    - Declined to participate (n=...)

- **3-Week Run-In**
  - Randomized (n=...)
    - Excluded
      - Not meeting Run-in criteria (n=...)
      - Declined to participate (n=...)
      - Refused to be randomized (n=...)

- **Allocation**
  - **Group 1 CONTROL**: Allocated to intervention (n=...)
    - Received allocated intervention (NA)
    - Did not receive allocated intervention (give reasons) (NA)
    - Discontinued intervention (n=NA)
    - Lost to follow-up (give reasons) (n=...)
    - Analyzed (n=...)
      - Excluded from analysis (give reasons) (n=...)
  - **Group 2 REGULAR**: Allocated to intervention (n=...)
    - Received allocated intervention (n=...)
    - Did not receive allocated intervention (give reasons) (n=...)
    - Discontinued intervention (n=...)
    - Lost to follow-up (give reasons) (n=...)
    - Analyzed (n=...)
      - Excluded from analysis (give reasons) (n=...)
  - **Group 3 PLUS**: Allocated to intervention (n=...)
    - Received allocated intervention (n=...)
    - Did not receive allocated intervention (give reasons) (n=...)
    - Discontinued intervention (n=...)
    - Lost to follow-up (give reasons) (n=...)
    - Analyzed (n=...)
      - Excluded from analysis (give reasons) (n=...)

- **Follow-Up**