HYP-FAST trial study protocol: a phase II, single-center, open-label RCT comparing the effect of early time-restricted feeding on blood pressure control versus standard of care in individuals with primary hypertension.

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APPENDICES

Appendix A - Study timeline
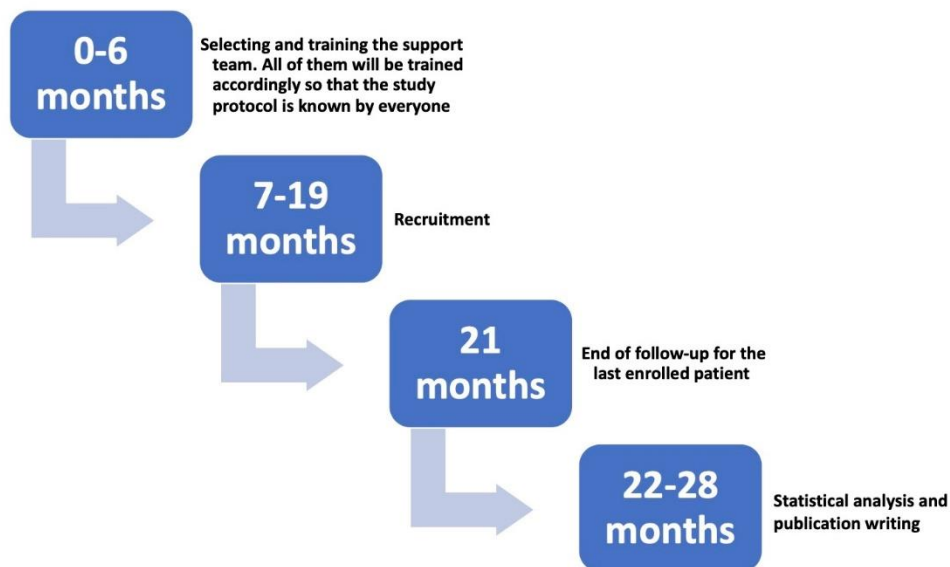
Image 1: Flowchart for the timeline over 28 months

Appendix B - Adherence strategies

Technique	Strategy
Motivational group session	Optional group sessions will take place in the hospital once a week. If attendance exceeds the maximum number of participants permitted by the social distancing policy, additional community centers will host group sessions. Group meetings will be live-streamed for participants via the password-protected Zoom platform. Group sessions for intervention and control groups will take place on different days to avoid data contamination. Both groups will receive standardized nutritional educational information and space to share their experience, and motivational group support. Group sessions are optional, and not attending will not lead to exclusion.
Telephone follow-up sessions	Weekly scripted telephone follow-up sessions will provide individual support to all patients during the trial (motivational interviewing and reinforcement session) (Rickman et al., 2011; Willis, 2019). The script will comprise questions related to adherence, challenges faced during the week, the presence of adverse events, and protocol deviations.
Physician and protocol consultation	A consultation with a physician will take place during all in-person follow-up appointments. During these appointments, BP measurement via a 24-hour ambulatory BP device, blood sample collection, weight measurement and evaluation of adverse events will occur.
Cell-phone Application	A mobile application will be used to monitor adherence. Subjects will be asked to register the hours of fasting daily. Reminders will be sent through the application to notify the beginning and end of the fasting hours.

Table 1: Techniques to maintain adherence

Appendix C - Definitions

Term/ monitoring strategy	Definition/ details
High-normal or hypertensive blood pressure	Three times repeated upper arm systolic BP measurement > 130mmHg or diastolic > 85mmHg, with at least two minutes interval between measurements and five-minute rest before measurement.
Food Records	At baseline, a nutritionist will provide instructions to each participant on how to complete the food records and follow the fasting intervention. Instructions will include information and guides to estimate portion sizes and record food items. This will be done through a video so that all subjects receive the same information. Subjects will not be required to weigh foods but will be asked to measure the volume of foods consumed with household measures (i.e., measuring cups and spoons). Both arms will complete a 24-hour food record at week 4 and 8.
24-hour blood pressure monitoring (ABPM)	Predetermined thresholds for daytime and night-time will be used as follows: BP will be measured every 20 minutes between 8 am and 10 pm (daytime) and every 30 min between 10 pm and 8 am (night-time). Participants will be told to engage in their usual activities during the measurement period. After the 24-hour recording, ABPM will be considered successful if at least 70% of the readings are successful: a minimum of 20 out of 42 daytime readings and 7 out of 20 night-time readings are successful. Successful measurements are defined by the BP measurement device.

Table 2: Definitions and additional monitoring strategies