
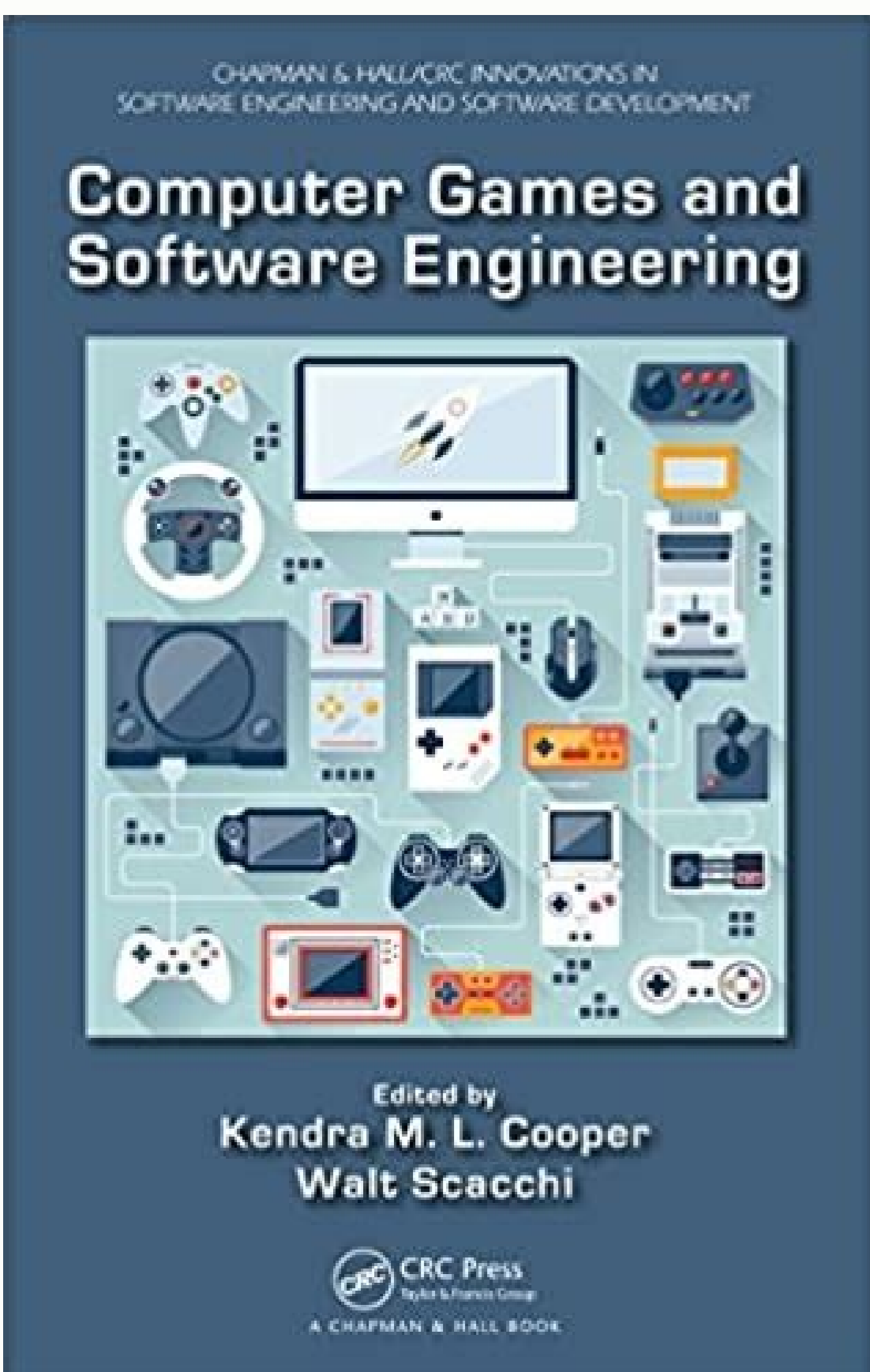
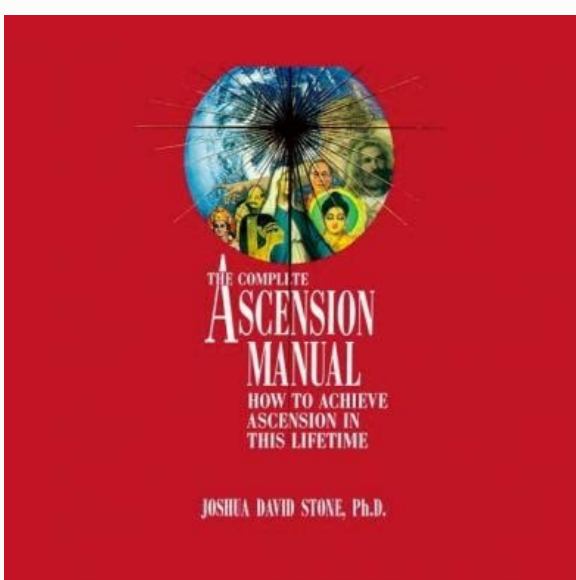


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Men undergoing surgery will also attend clinic for flow rate testing 4 months after operation. The study will be conducted in accordance with the recommendations for physicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions. SponsorNBT will act as the Sponsor for this trial. These include: ■ Long-standing BPO might impair bladder contractility, reducing the symptom benefit of surgery ■ BPO-relieving surgery increases the calibre of the outlet channel regardless of whether BPO is present, and this might improve urinary stream in men who technically did not have BPO ■ A 'placebo effect' is known to arise both from clinical contact and from the surgical procedure ■ Whilst voiding LUTS (obstruction) typically improves after surgery, this advantage will be offset in some men due to deterioration in storage LUTS (e.g. incontinence, overactive bladder) We therefore anticipate the overall IPSS at 18 months in both arms might be similar despite group differences in surgery rates. However, to ensure that the men in the urodynamic arm are not disadvantaged by the reduction in surgery rates, we need to ensure that the primary outcome, symptom score, has adequate power to rule out non-inferiority. Randomisation will be stratified by centre. Blinding/Blinding in the urodynamic unit is not possible nor appropriate in this pragmatic trial, given that men are only catheterised in the invasive group, hence group allocation cannot be concealed from the man or the staff. If the patient has changed his mind, however, and no longer wishes to be randomised, the research centre should complete the 'UPSTREAM Change of Permissions/Withdrawal Form' accordingly, and follow essential reporting procedures specified on the form. This will be adapted for dissemination through public channels. In addition, the PMG will also meet at the Trial Steering Committee meetings. Trial Steering Committee (TSC) The role of the TSC is to monitor and supervise the progress of the trial. Secondary outcome measures ■ Surgery rate (the relative proportion of men in each group having surgery up to 18 months after randomisation) ■ Cost-effectiveness analyses from the perspectives of the NHS, personal social services and patients. Therefore, at the request of the TSC, we revised the accrual projections based on a more realistic assumption conditioned both on differential recruitment by centres over time and recruitment capacity. Subsequently, a further internal feasibility phase was conducted between February and April 2015 with a revised target of 42 participants from 4 centres, with additional reporting to the TSC upon conclusion to gain a realistic assessment of recruitment. Our recruitment target will be 400 per arm with the aim of achieving no less than 388 per arm at 18 months follow-up. Statistical analysis Baseline characteristics will be examined at baseline to ensure randomisation has provided the two pathways with patients that are comparable on equal terms. IPSS is validated [23], well-known and widely used in the NHS. The PP will be invited to meet with the CI and/Project Management Group (PMG) on a monthly basis in the setting-up phase and at the conclusion of the study, and quarterly at other times (or more often if needed). The UPSTREAM online database should also be updated accordingly by the local research centre at the earliest opportunity. Furthermore, knowledge of the



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